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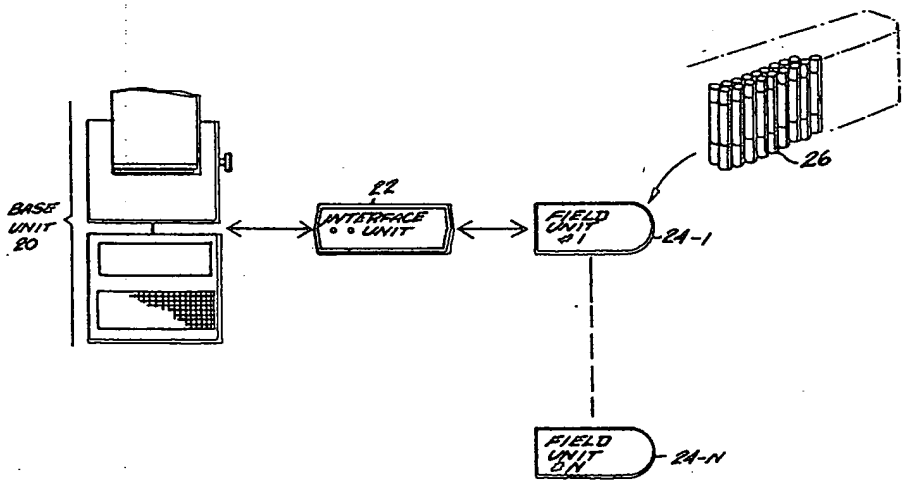

(57) Abstract

The invention relates generally to the art of controlled dispensing and compliance monitoring. Prior art devices relating to medication compliance monitoring lack the necessary control mechanisms to administer complex drug regimens to patients. The present invention overcomes the deficiencies by providing a controllable dispensing device for use by a drug therapist for the unsupervised administration to a patient of a drug therapy regimen. A field unit (24) is loaded with a plurality of medication containers (52) in a predetermined sequence. Along with the medication, a program of dosing times is stored in electronic memory (102) of the field unit. This program is defined using a computerized base unit (20) and is transferred to the field unit via an interface (22) between the base and the field units. The field unit includes a display (204) and alarm (208) for alerting the patient as to the times for dispensing and administering the medications in the containers. The field unit permits dispensing of containers only in accordance with the predefined dispensing. Later, the field unit can be debriefed by the base unit via the interface and the base unit prepares a report of medication compliance for the drug therapist.

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CONTROLLED DISPENSING DEVICE

BACKGROUND OF THE INVENTION

Field Of The Invention

This invention relates generally to the art of controlled dispensing and compliance monitoring. It has particular application to the art of unsupervised drug dispensing to a patient although the principles of the invention apply to controllable dispensers of any types of material. The presently preferred embodiment of the invention provides a controlled medication dispenser. The dispenser can be preprogrammed by a drug therapist using a base unit (specially programmed computer) to which the dispenser is temporarily coupled, to permit a patient access to drugs stored in a portable field unit only in accordance with predetermined criteria, such as for example at particular times. A digital display on the dispenser specifies the next dosing time and will instruct the patient on proper make-up doses in the event of missed doses. The portable field unit records actual times of medication dispensing and can easily be debriefed by the base unit (computer) which then prepares a medication compliance report for the drug therapist.

Background Of The Invention

"Controlled dispensing" refers to the concept of permitting a user to dispense some item according to a predetermined schedule or set of rules, rather than permitting unrestrained access. A significant application of the art of controlled dispensing relates to drug dispensing.

"Compliance monitoring" refers to the concept of recording a user's actual dispensing activity compared to a previously prescribed regimen. A significant application to the art of compliance monitoring also relates to drug therapy.

As drug research and therapy become more and more sophisticated, drug researchers and therapists have an increasing need to administer complex drug regimens to patients; to restrict access to medications in some instances; and to evaluate the patients' compliance with those drug regimens.

The most accurate way of administering a drug regimen and measuring compliance of a patient or test subject is direct supervision of each dose of medication. The manpower required for this type of drug administration is extraordinary and usually requires hospitalization. The alternative of prescribing a drug regimen and leaving it completely to the patient to follow and report back usually results in poor compliance and inaccurate reports.

Controlled drug dispensers and compliance monitoring equipment provide a middle ground between direct supervision and no supervision so that relatively dangerous drugs can be administered without direct supervision and clinical drug studies can be carried out with relatively high reliability.

As the U.S. Department of Commerce National Technical Information Service Publication PB-278 973 entitled "Possible Designs of Medication Monitors", prepared at the National Jewish Hospital and Research Center, Denver, Colorado, for the American Lung Association (April 1978) points out, the genesis of the medication compliance monitor goes back to May 1962. This early concept was for a

medication monitor utilizing radioactive material and photographic film to determine when patients removed medication from a medication dispenser.

Since then there have been several publications on different devices utilizing the same principle, as well as field trials. Since the original publication, the interest in the field of patient compliance with drug regimens grew enormously.

"The Unrealized Potential of The Medication Compliance Monitor" was discussed by Thomas S. Moulding, M.D., at the National Jewish Hospital in a February, 1979 commentary appearing in Volume 25, November 2, of Clinical Pharmacology and Therapeutics. That commentary provides some insight to the historical development of the art of medication compliance monitoring. This Moulding commentary discusses an early version of a radiographic-type compliance monitor. As medication compliance monitoring further developed, various arrangements appeared in the literature and marketplace. Moulding describes a radiographic compliance monitor capable of showing dosing patterns. Each container holds a full daily dose of medication. However there is not provided any alerting features to help the patient to remember to take dosages. Processing and interpreting the compliance record are awkward. Potential hazards are associated with the use of a radioactive source. No control mechanisms are used -- Access is not controlled nor is the number of dosages taken at one time.

Moulding anticipates the use of strip packaging and microprocessors for improving compliance monitors' design but no practical details

are given on how to accomplish these design improvements. It does not appreciate the utility of a device capable of delivering multiple medications in complex regimen. The commentary does not teach how to build a reliable and tamper-proof dispensing mechanism; a successful strategy for field, interface, and base unit electronics and software is not given.

Lederle Laboratories (American Cyanamid Company) developed a digital module for the cap of a medicine bottle for reminding the patient when he last took his medication. This "reminder" cap was intended to help people to take medication at the proper time. However, such an arrangement has certain fundamental inadequacies: The clock does not indicate when the next dosage is due. The patient must still remember the proper dosage schedule. There is no alarm to get the patient's attention when the next dosage is due. The cap has no memory to show the therapist when dosages were taken. There is no control over when the bottle cap is opened or the number of dosages taken after the cap is removed. Also, multiple caps are needed for multiple drug therapies; and the patient is not guided as to how much of each drug is to be taken.

A "Med Tymer" medicine bottle cap was developed by Boston Medical Research, Inc. It includes preprogrammed light and sound alarms that announce when the next dosage is due. 1/day to 4/day schedules are available. However, it also has several functional limitations. Programs are in firmware and are not adjustable. Thus, there is no flexibility of dosing times for a given daily frequency. The cap has a limited lifespan (12 months) and is not reusable or reprogrammable. It

is not approved for liquid medications. It has no memory for later reporting of compliance. There is no control over when the cap is opened or the number of dosages taken after the cap is removed. Multiple caps are needed for multiple drug therapies; and the patient is not guided as to how much to take of each medication.

In an article entitled "Medication Monitor for Opthamology" by Yee et al appearing at page 774 of the American Journal of Opthamology, there is described a medication monitor wherein dosing times are recorded in memory for later reporting of compliance. Its functional limits are as follows. There are no alerting features such as an alarm, or clock displays, etc. The electronics provide only a limited memory, i.e. there is no microprocessor to provide alarm and control functions and the limited memory results in limited dosing record resolution. It is only possible to achieve one hour resolution of dosage taken times; and multiple doses within any given hour cannot be recognized. There is no control over when the cap is opened or the number of dosages taken after the cap is removed. Multiple units are needed for multiple drug therapies; and the patient is not guided as to how much to take of each medication.

A sample of the patent literature in this art includes:

U.S. Pat. 3,369,697, Glucksman et al, Feb. 20, 1968
U.S. Pat. 3,968,900, Stanbuk, July 13, 1976
U.S. Pat. 4,223,801, Carlson, Sept. 23, 1980
U.S. Pat. 4,293,845, Villa-Real, Oct. 6, 1981

SUMMARY OF THE INVENTION

The present invention provides a controllable dispenser having significantly improved operational features over known dispensers.

The dispenser's operation is based upon a packaging concept that places containers along a flexible strip in a predetermined order. The containers may be attached to the strip in various ways. For example, the containers may be integral to the strip material itself, or they could be placed in pockets or sleeves formed in the strip material. Strip materials are typically plastic films that have been heat sealed to form the container holding pockets or adhesive backed fiber tapes sandwiched around non-sticking sleeves, although many other combinations of materials could provide the same effect. More rigid materials could be used for strip construction, but much more efficient container storage is possible if the strip material is flexible enough to allow the containers to be positioned such that neighboring containers are touching one another. Strip flexibility is also beneficial in insuring smooth movement of the strip around turns in the storage volume. Strip materials should not be so weak that tensile forces occurring during the dispensing operation stretch the strip and alter important container spacing intervals.

Container attachment points are spaced at intervals along the strip that correspond to engagement location spacings on the dispensing mechanism. These strip and dispensing mechanism spacings permit a rack and pinion type of dispensing operation. Although almost any spacing

interval may be chosen, minimal spacing limitations will arise for given container packing arrangements. For hexagonal closest packing arrangements (as shown in Figure 4), the minimal spacing between containers is approximately one-third the container circumference. Using the nomenclature of Figure 3, $Smin \geq C/3$. Parallel packing arrangements (as shown in Figure 5) require a spacing length of at least one container diameter, $Smin \geq d$.

Various container shapes and sizes may be accommodated by the dispenser's structural arrangement. Depending upon storage volume design and the shapes of parts of the dispensing mechanism, containers having square, semicircular, or other cross-sections may be acceptable. However, circular cylinders are particularly useful containers, having a shape that packs efficiently for storage, moves freely through the storage volume passageways without jamming, and is reliably engaged by the dispensing mechanism. Containers may be made of any rigid or semi-rigid material. Although more flexible container walls can aid the containers in passage through the storage volume and the dispensing mechanism, too flexible materials might prevent the container from maintaining the approximate shape required for proper engagement by the dispensing mechanism.

Varying container volumes are accommodated by merely changing the length of the container. Since the container cross-section remains the same, a dispensing device design is then possible that accommodates various container volumes by merely changing the height of the storage volume and ejector mechanism. No changes

to the design of the dispensing mechanisms are necessary.

The packaging system of this invention offers several advantages over previously known arrangements. The dispenser is useful for dispensing various kinds of materials, but it is particularly useful for medication dispensing. A wide variety of containers having various diameter to length ratios may be used. By using a container that is leakproof and has a relatively wide opening, a single dispensing device may be used in several different applications. For example, the leakproof 5cc vials used in the medication dispenser/monitor/controller implementation of this design will accommodate almost any medication presentation, including: liquids, suspensions, salves, tablets, capsules, devices, and even multiple compatible substances within a single vial. Further flexibility is provided in that other container volumes can be accomodated by merely changing the length of a container with a given cross section. Only the height of the storage base and ejector pinion need then be changed. Thus, the design and size of the device's dispensing module (containing the electronics and dispensing mechanisms) and the spacing intervals of the flexible strip do not change. One dispensing module may be used with several storage bases and ejector pinions to provide a wide range of container capacities and optimized (minimal volume) package sizes.

Another significant feature relates to individual packaging.. The proper amount of the substance to be dispensed is placed in individual containers instead of allowing the user access to

a bulk supply and relying upon him or her to dispense the proper amount. The amount of the substance to be dispensed is precisely metered into the individual containers by the pharmacist/therapist and can be double checked before the device is handed to the user. The same metering precision and reliability over many dispensing operations is not likely to occur when the user must do the measuring or a mechanical device must repeatedly measure and dispense from a bulk supply.

Using individual containers helps prevent contamination and cleaning problems and thereby enhances the economics of such a reusable system. The dispensing device can be used for dispensing one type of substance and, upon completion of the first dispensing program, be immediately reloaded with vials containing a different substance with very little chance of cross-contamination and no substantial cleaning requirements. Bulk or even compartmentalized storage volumes would need extensive cleaning before reuse.

Complete control over dispensing sequencing is provided. The capability of varying the amount and types of substances within each container and organizing these varying contents into a predetermined sequence is a primary feature of the invention. Using the medication dispenser/monitor/controller example, the device could be loaded with vials containing various combinations of drugs in the proper sequence such that a patient on multiple regimens will receive the proper selection of medications according to

the prescribed schedules, and without the patient having to remember any dosing details.

The sequencing feature may also be used to deliver increasing or decreasing amounts of one or more substances over the dispensing period. Thus, a physician using the medication dispenser/monitor/controller to administer medications can taper dosage levels and thereby deliver more effective therapeutic levels while simultaneously minimizing side effects in a manner not possible using level doses.

The dispenser according to the invention is tolerant of any positional orientation. Unlike gravity feed devices, the dispensing device according to the present invention will operate properly in any orientation. The container strip maintains container sequencing and proper spacing regardless of position. Some storage volume characteristics, described later, also help prevent undesirable container movement and thereby contribute to the device's orientation tolerance.

The packaging of containers along a flexible strip forms a flexible rack-like device that, in combination with the pinion-like dispensing mechanism described below, permits the construction of a very compact and reliable dispensing device.

The primary dispensing mechanism includes an ejector element mounted for rotation about its longitudinal axis and having container conforming depressions positioned around its periphery. The ejector acts as a pinion gear that drives a flexible rack, the container strip. When the ejector is rotated, one container is moved from a ready position and out of the dispenser while,

simultaneously, the next container to be dispensed is engaged by a mating ejector depression and moved into the ready position.

Thus, the pinion, the ejector element having depressions that form gear-like teeth, is fixed, and the rack, a flexible strip with attached containers acting as the mating gear teeth, is moved out of the device by pinion rotation. This design offers many advantages:

The first of these advantages is reliability. Using the containers as the 'teeth' on the rack provides inherently more reliable pinion engagement than a conventional flexible strip with rows of small holes used to engage pins on the pinion (as in camera film for instance). Accurate engagement location spacing is essential to jam free operation in both cases. However, the container as sprocket design has only one critical spacing per dispensing operation, whereas for a multiple hole rack, several accurate hole to hole intervals are needed for the same single dispensing operation. Strip manufacture is also simplified by using the containers as sprockets. Punching the multitude of precisely positioned small holes is not required.

The mechanism operates simply. A 1/4 turn of the ejector pinion is all that is required to accomplish a dispensing operation. The container is then outside the device where it can be slid out of its sleeve for use and the empty strip is torn off across the opening edge.

As discussed above, the same dispensing mechanisms may be used to dispense various volume containers merely by changing the length of the ejector pinion to correspond with the associated

container length. Like the container strip, the dispensing mechanism may be operated from any position.

Completed dispensing operations are signalled to a microprocessor by means of lever switches activated by spring loaded actuators riding cams on the shaft used to drive the ejector pinion. The mechanism is designed to activate the signalling switches when the user has completed the 1/4 turn drive shaft rotation. False signals are prevented by using two switches that are alternately, mechanically activated by cams 90° apart and by alternately arming the switches electrically by means of microprocessor output ports. Thus, as soon as a particular switch is activated mechanically, it is deactivated electrically immediately after the signal is received so that further minor motion of the ejector driveshaft is not improperly interpreted as another completed dispensing operation. Simultaneously, the other switch is electrically armed so that it will signal the microprocessor upon the next 1/4 turn rotation and ensuing mechanical activation.

The flexible rack and pinion mechanism described above is the basis for a superior dispensing system having the advantages discussed above. However, in situations requiring the utmost reliability and control, such as the medication dispenser/monitor/controller application, further mechanical and electromechanical features can greatly enhance reliability. The features listed below may be used separately or in various combinations as

required to insure reliable operation in a particular dispensing situation.

The first group of features relates to the housing. The dispensing device components may be housed in two sections. The lower section, the storage base provides a storage volume for the container strip and retains the ejector pinion. The upper section, the dispensing module 46, houses the electronics and all the dispensing mechanisms other than the ejector pinion 34. Both housings may be of one piece, fastenerless construction. The two housing parts are held together by a cabinet lock mounted in the dispensing module, and having a key operated cam that engages slotted extensions of a partition 30 in the storage base. This construction provides several beneficial features.

The tongue and groove mating of the upper and lower housings allows a simple one point locking design having a tamper-resistant joint. Since the user is not given the key to the cabinet lock, there is no easy access to the contents of the dispensing device other than through proper manipulation of the ejector mechanism. Both the storage base and dispensing module are free of external fasteners so that tampering is discouraged and difficult to hide if attempted. The opening in the storage base where containers are ejected is protected against intrusion by the design of the ejector pinion. The sprockets of the ejector pinion are such that they form a close fitting barrier with the storage base partition and thereby prevent viewing of and access to the next container to be dispensed.

There are no unsealed openings in the top of the device through which spilled fluids could reach the electronics and mechanisms. The tongue and groove method of joining top and bottom housings further protects against spills. Since all the electronics and all the dispensing mechanisms except the ejector pinion are mounted in the top housing, any leaking containers are not likely to contaminate those elevated regions. Further protection against leakage contamination can be easily attained by sealing a cover plate over the bottom of the dispensing module, thereby protecting all mechanisms and electronics with one simple cover. A coating provided over the electronics can provide additional protection.

Smooth, jamproof, container strip movement is a feature of the storage base design. As shown in Figure 4, the storage base outer wall and inner partition form a generally U-shaped storage volume in which containers are packed both inside and outside the partition. This design provides exceptionally efficient (compact) container storage while simultaneously providing passageways through which the container strip can move smoothly without jamming.

By keeping all passageways a little less than two container diameters "d" (See Figure 3) in width, containers cannot get past one another and out of sequence. Thus, impact forces cannot rearrange container sequencing and cause containers later in the sequence to engage the ejector pinion ahead of earlier containers and jam the mechanism. Because a minimum passageway width of 1.87 diameters is needed to allow double row, closest packing as is desired in some areas, the

passageway widths in those regions are typically kept between 1.87 and slightly less than two (2) diameters.

The U-shaped design allows for smooth container strip movement since there are only two partition turns, at a maximum, for the containers to negotiate. The radii of the turns are large enough, compared to the inter-container spacing, so that most contact with the partition is by the containers and not the spacing intervals. Because the containers only have line contact with the partition wall, very little frictional force is generated and the containers move smoothly around the turns. Tighter radii would allow more strip contact with the partition wall and produce larger drag forces that might bind strip movement. Circular storage volumes, having capacities as shown, are not preferred because they have housing proportions that are hard to hold in one hand. Similarly, even though longer, rectangular designs can have fewer turns, the extended housing length can make portable units awkward to carry.

The two part housing design is also beneficial to the user who may want the capability of dispensing several different capacity containers with a minimum equipment investment. Since all electronics and mechanisms other than the ejector pinion are contained in the top half dispensing module, container capacity can be changed merely by using a container of the appropriate length to give the volume desired, and by using a storage base and ejector pinion of corresponding length. No change in dispensing module size or design is required. Thus, one dispensing module can be used with several

different height storage bases, ejector pinions and containers to produce a broad capability dispensing system.

There are several mechanisms associated with control of ejector pinion motion that help insure reliable operation.

A pin 92 located in the storage base (See Figure 22), under a groove in the ejector pinion, prevents further ejector rotation until the dispensed container is removed. This pin prevents inadvertent, or intentional, attempted insertion of containers back into the unit which could jam the ejector mechanism.

The two alternately acting ejector switch actuators described above have a second function. The depressions in the drive shaft that engage the spring loaded actuators are shaped so that the drive shaft cannot be turned in the reverse direction once an actuator has seated. Thus, the drive shaft can be turned backwards at most something less than one-quarter turn and not at all once the fully dispensed position is reached. By preventing reverse ejector rotation, containers are prevented from being intentionally or inadvertently pushed back into the storage volume and thereby possibly jamming the dispensing mechanism, or disengaging the ejector pinion.

Pins are arranged in the top of the ejector pinion such that they extend into the dispensing module. A notched locking wheel 86 is positioned in the top housing so that its circumference will prevent ejector pinion rotation unles the notch is so aligned as to allow the adjacent ejector pinion pin to rotate forward. The notch is so designed that as the ejector

pinion rotates forward a pin engages the notch well and forces the locking wheel to rotate before disengaging the notch. Once the locking wheel is turned, the notch is no longer in a position such that the next ejector pinion pin can move forward, and the ejector pinion is thereby locked.

Thus, ejector pinion locking occurs automatically and mechanically each time a container is dispensed. This auto-lock feature prevents the operator from inadvertently dispensing too many containers by rotating the ejector pinion more than 90 degrees. Being mechanical and automatic, the mechanism requires no computer logic or power to perform this function. This locking design also permits a simple, but effective, computer controlled unlocking feature that can be used to better insure operator conformance to a predetermined dispensing schedule.

Where restricted access to the containers is not important, a simple mechanical linkage can allow the operator to manually reset the locking wheel so that the notch is aligned to permit another dispensing operation. In other situations, where precise control over the dispensing operation is desired, a solenoid 212 controlled by the dispensing device's microprocessor can be easily put in control of the locking wheel. When an electrical pulse is supplied to the solenoid, it rotates the locking wheel 86 in the reverse direction (approximately 45° in this example) so that the notch 90 is moved into the unlocked position.

Although a linear acting solenoid with linkages can be used to reverse rotate the locking

wheel into its unlocked position, no linkage is necessary if a rotary acting solenoid is used and a simpler, more reliable design results. The choice of a rotary solenoid over a linear solenoid also greatly increases the impact resistance of the dispensing mechanism. Linear acceleration/deceleration forces (due to impacts, for instance) in the direction of the longitudinal axis of the plunger of a linear solenoid could cause the locking mechanism to lock or unlock when not intended. Since linear forces produce balanced and opposed forces when acting on a rotational mass, impact forces do not tend to cause inadvertent armature motion when a rotary solenoid and locking disc are used.

Further means of insuring that lock/unlock positions of the locking wheel are retained can be provided through the use of latching forces. Latching mechanisms increase the force required to move the locking wheel out of either one of its bistable positions. One form of the latching mechanism utilizes three magnets: one on the locking wheel, and two others mounted such that they are adjacent the locking wheel magnet and providing attractive (latching) forces when the wheel is in its lock and unlock positions. Although there are many other possible latching designs (such as spring loaded rockers), the described magnetic system uses just three simple parts that can be easily adjusted to provide the optimum latching forces. By adjusting the magnets' residual field strengths during magnetization, the resultant latching forces may be made just sufficient to prevent accidental motion of the locking wheel with no excess force

that would require the use of a larger and higher power consuming solenoid. Since a rotary solenoid greatly reduces the latching forces required because of its inherent stability under linear forces, the torque requirements of the design are minimal.

A lever switch ("status" switch) adjacent a cam on the locking wheel is used to signal to the microprocessor the status of the locking/unlocking mechanism. This provides a check to see that the locking wheel has been able to respond properly to commands from the microprocessor. If, for instance, the user has prevented locking wheel reset by applying restraining forces through attempted drive shaft rotation during the solenoid pulse, this switch will alert the microprocessor to the need for sending additional pulses to the solenoid until the unlocking operation has been successfully completed.

The dispensing device described above can certainly perform all its functions, with all the stated benefits, from a fixed location using externally supplied power. However, the structure has been particularly optimized for portable operation using self contained batteries. Portability is especially beneficial to the medication dispenser/monitor/controller application where small size and battery operation are essential.

Several features contribute to efficient utilization of space within the unit:

a. Hexagonal, closest packing - much of the storage volume is configured for double row, closest packed storage which results in maximum

container densities. The flexibility of the container strip allows the containers to be pushed next to one another to accomplish closest packing.

b. Optimum partition design - the U-shaped partition folds the container strip into a compact area while providing large radius turns that help insure smooth strip movement. Virtually the entire area inside and outside the partition may be filled with containers. Single row designs, such as one using a spiral partition in a round enclosure, require more extensive partitions that waste space and have more turns that increase the undesired drag forces on the strip as it is advanced. On the other hand, use of too few partitions risks the possibility that containers will not advance in the proper order and thereby jam the dispensing mechanism.

The U-shaped design also affords the most easily grasped and carried device proportions. Round devices having comparable capacities have diameters that are too large to comfortably grasp without a handle. More rectangular designs of similar capacity have a length dimension that becomes more awkward to accommodate during transport and storage.

c. Minimum wall thickness - The outer wall and partition thicknesses have been minimized to save volume and weight. Using extensions of the storage base partition, instead of a base mounted post, to engage the upper housing cabinet lock maximizes the space available for container storage.

d. Housing adaptability - The placement of all electronics and dispensing mechanisms in the top portion of the device allows the height of

the separate storage base to be adjusted to exactly fit the height of the containers.

e. VLSI circuits - Very large scale integrated circuits are used, each of which perform the function of several circuits in just one package, thereby saving large circuit board areas and reducing unit weight.

f. Plastic construction - Almost all housing and support structures, as well as several of the dispensing mechanisms, may be suitably constructed of plastic materials, thereby lessening the weight that must be carried.

g. Software features - By implementing in software several functions normally implemented in hardware, valuable space and weight are saved. The usual UART (Universal Asynchronous Receiver/Transmitter) and parallel interface hardware elements have been implemented in software. Serial communications are used to simplify the hardware necessary for communications with the Base Unit. The level shifting circuitry needed by the communications link has been moved out of the dispensing device and into the Interface Unit to save more dispensing device space.

So that the dispensing device could be used in applications such as the medication dispenser/monitor/controller where the battery power supply must provide up to 60 days or more of continuous operation, many power saving features have been implemented.

a. CMOS circuitry - All integrated circuits are of Complementary Metal Oxide Silicon construction for lowest possible current draw.

b. 'WAIT' mode - The use of a microprocessor having a low power standby operating mode and software that places the MPU in that power saving mode for more than 98% of its operating period is the major power saving feature.

c. Piezoalarm - The reminder alarm function is implemented with a piezoelectric element that uses only a few milliamperes of current. Further power savings result by only pulsing the alarm for a fraction of every minute.

d. LCD - A liquid crystal display is used as the visual dispensing reminder because it uses only microamperes of current.

e. Mechanical auto-lock - The auto-lock feature requires no electrical power, the motive force being supplied by the dispenser operator while advancing the ejector pinion drive shaft.

f. Manual ejector drive - Although the ejector pinion could be motor driven to ease the dispensing operation for the fixed location user where external power is readily available, the manual drive design permits portable operation where the large amount of power required for an electric drive is not available.

g. Rotary solenoid - As described above, a rotary solenoid requires less latching forces and therefore less starting torque (power) than a linear solenoid design. Rotary solenoids also provide superior starting torque for a given current and size. The unlock mechanism is designed so that the unlock solenoid need merely rotate a lightweight locking wheel. No linkage forces have to be overcome that would require the use of a bulkier, higher current draw solenoid.

Further, the solenoid driving software routine sends only a 50 msec pulse of power to the solenoid, limiting power used to the minimum needed to accomplish reliable unlock operation. Only pulses of power need be sent to the unlock solenoid since the mechanism is latched once it reaches the unlock position and no further power is needed to maintain the proper position.

h. VLSI circuitry - The use of highly integrated circuits reduces power consumption compared to discrete devices performing the same functions.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a block diagram of the medication dispenser and compliance monitor system according to the present invention;

FIGURE 2 is an exploded, partially cut-away view of a field unit 24;

FIGURE 3 is a schematic representation of containers on a strip showing dimensions and spacings;

FIGURE 4 is a top view of the storage base portion of the Field Unit showing containers to be dispensed stored therein;

FIGURE 5 is a schematic representation of an alternative container storage arrangement;

FIGURE 6 is a schematic representation of an integral strip and storage container;

FIGURE 7 shows a strip arrangement including two portions heat sealed to one another;

FIGURE 8 shows a two portion strip 50 with a container held between the two strip portions;

FIGURE 9 shows a container with a separate plug cap;

FIGURES 10-12 are schematic diagrams showing a dispensing operation;

FIGURES 13 and 14 are side views of a portion of the dispenser module showing how a dispensing operation is signalled;

FIGURES 15 and 16 are schematic views further illustrating how a dispensing operation is signalled;

FIGURES 17-19 are schematic illustrations demonstrating the automatic locking mechanism;

FIGURE 20 is a side view showing the operation of the locking wheel by the rotary solenoid;

FIGURE 21 is a top view of ejector pinion 34 showing the position of the container stop pin;

FIGURE 22 is a cross sectional side view showing the position of the container stop pin;

FIGURE 23 is a cross section view of the assembled Field Unit;

FIGURE 24 is a view looking up at the dispensing module portion of the field unit;

FIGURES 25 a and b are a schematic diagram of the electronic subsystem of the field unit;

FIGURE 26 is a flow chart of the software controlling the operations of the field unit;

FIGURE 27 is a schematic diagram of the interface unit 22;

FIGURE 28 is a block diagram of base unit 20;

FIGURE 29 is a flow chart of the base unit loading routine software for loading a field unit;

FIGURE 30 is a flow chart of the base unit unloading routine software for debriefing a field unit after it has dispensed some or all of its containers;

Appendix I is a detailed listing of the software controlling the field unit;

Appendix II is a detailed program listing of the loading routine shown in flow chart form in figure 29; and

Appendix III is a detailed program listing of the debriefing routine shown in flow chart form in figure 30.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

System Overview

Referring first to FIGURE 1, there is shown a block diagram of the overall system concept of the present invention. The system includes a single base unit 20, a single interface unit 22 and a plurality of field units 24-1 . . . 24-N. A drug therapist or researcher can program many field units 24 (one at a time), give them to different patients or subjects and later collect and debrief them and prepare compliance reports.

To prepare a field unit 24 for distribution to a patient or test subject, a medication package, such as package 26, is first loaded into field unit 24. The field unit is then electrically connected with interface unit 22 and a programmed drug regimen, defined by the therapist by interacting with base unit 20, is loaded via interface 22 into the field unit. The drug therapist defines the drug regimen by using

the "LOAD-M" software (set forth in Appendix II) with base unit 20 to configure the field unit 24.

The loaded field unit 24 is given to the patient, who dispenses medication in accordance with the schedule loaded into it using the "LOAD-M" software. The dispensing operation is governed by the software stored in field unit 24 and listed in Appendix I. This field unit software provides dosing time prompts, controls the dispensing mechanism, and stores the actual times and dates of dispensing.

After the drug regimen is completed, field unit 24 is returned to the therapist where it is again connected to base unit 20 via interface 22. The field unit is then debriefed according to the software listed in Appendix III and the base unit prepares a report to the therapist as to exact times of dispensing and any departures from the desired schedule.

Field Unit Mechanics

Referring to FIGURES 2-24 there are shown the mechanical details of a field unit 24.

Referring first to Figure 2, there is shown an exploded view of field unit 24. Field unit 24 includes a storage base 28 constituting a portion of the housing of the field unit. Inside of storage base 28, there is fitted a storage base inner partition 30 which, together with an outer wall 32 of the storage base defines a passage way within which a dispensing package 26 can be stored and from which individual containers can be dispensed. The dispensing action is carried out by the rotation of an ejector pinion 34 which is manually rotated by the user by manipulation of a

knob 36, during times when the field unit is "unlocked" in accordance with a predetermined dispensing schedule stored in it. The unlocking mechanism operates under microprocessor control as will be described later in further detail.

Inner partition 30 includes two slotted extensions 38 and 40 which pass through a hole 42 in a plate 44 and ultimately engage with a cam lock (not shown in Figure 2) in a dispensing module portion 46 of Field Unit 24. Dispensing module portion 46 includes various mechanical elements, electronic subsystem, display, alarm, etc. A slot 48 on the upper surface of dispensing module portion 46 accommodates a key for a cam lock.

Dispensing package 26 includes a strip 50 holding a plurality of individual containers 52, each having its own cap 54. Package 26 is fitted into the passageway defined by outer wall 32 and inner partition 30 of storage base 28 according to a predetermined sequence. Each time a container 52 is to be dispensed, ejector pinion 34 is rotated so as to engage a single container 52 and push it through an opening 56 in outer wall 32 of storage base 28. Ejector pinion 34 is rotated by the user by means of rotating drive shaft Knob 36.

Ejector pinion 34 includes four locking pins 58 which cooperate with an unlocking arrangement for controlling when ejector pinion 34 can be rotated in accordance with the pre-determined schedule. Ejector pinion 34 includes four concave portions 60 for accommodating the shape of individual containers 52 so that a container fits within concave portion 60 and is conveyed by rotation of the ejector pinion.

Referring now to Figure 3, there is shown a schematic representation of a portion of a medication package 26 including strip 50 and two (2) containers 52. Each container has a circumference "c" and a diameter "d". There is a space "s" separating two adjacent containers 52.

Referring now to Figure 4, there is shown a top view of storage base 28 of field unit 24 with the dispensing module portion 46 removed. This figure shows a plurality of containers 52 packed within the passage way defined by inner partition 30 and outer wall 32. The arrangement of containers 52 shown in this Figure where the passageway is widest represents what is known as "hexagonal closest packaging" which allows the maximum number of containers 52 to be stored within the passage way volume. The minimum inter-container strip spacing required for closest packing is shown as the length Smin. The numbers shown inside each of containers 52 represent the sequence of dispensing of the individual containers. First, container #1 is dispensed, then container #2 is dispensed, etc. Each dispensing operation corresponds to a 1/4 turn of ejector pinion 34. As individual containers 52 are dispensed, strip 50 is pulled and the undispensed containers advance through the passage way as necessary toward ejector pinion 34.

Referring now to Figure 5, there is shown an alternative, but not preferred, packaging arrangement of containers 52 known as "parallel row packaging". The numbers inside each of containers 52 represent the sequence of dispensing of the containers. The minimum inter-container

strip spacing required for parallel row packing is shown as the length Smin.

Containers 52 can either be formed integrally with strip 50 as shown in Figure 6 or the containers can be fitted within spaces formed in strip 50 to accommodate the containers. As shown in Figure 7, strip 50 can be formed from two separate and distinct strips of material 62 and 64 which can be sealed adjacent to container areas. The individual containers 52 can then be inserted into the space defined by the two strips of material.

Referring to Figure 8, there is shown such an arrangement including strips of material 62 and 64 with a container 52 inserted therein.

Referring now to Figure 9, there is shown a more detailed view of a portion of medication package 26. Each container 52 can be fitted with its own plug cap 66.

Referring now to Figures 10, 11 and 12, there are shown top views of the portion of storage base 28 including ejector pinion 34. These figures illustrate the dispensing sequence for containers 52. As in the preceeding figures, the numbers shown in the centers of respective containers 52 indicate the dispensing sequence of containers 52. As shown in Figure 10, the first container is engaged in a concave portion of ejector pinion 34. This first container 52 is positioned along strip 50 in accordance with the details shown in Figure 3 with a spacing s between containers #1 and #2, the distance between concave portions of ejector pinion 34 also being equal to said length S. Ejector pinion 34 rotates in the direction shown by arrow 68. Figure 10 shows the

position of containers #1, #2 and #3 just before ejector pinion 34 is rotated its quarter turn to dispense container #1. In Figure 11, ejector pinion 34 has been rotated 1/8th turn from its starting position and container #2 is already engaged in the next concave portion of ejector pinion 34. Figure 12 shows ejector pinion 34 rotated a full quarter turn from its position shown in Figure 10 and with container #1 dispensed through opening 56 of storage base 28. For the sake of drawing convenience, in Figure 11, strip 50 is shown with some "slack" around Fig. 70 of ejector pinion 34. In reality, there would be little slack since the spacing S between containers is carefully selected so that there will be no slack. As shown in Figures 10-12, ejector pinion 34 conforms to the space defined by outer wall 32 and inner partition 30 so that there is very little clearance between the tips 70 of ejector pinion 34 and the wall and partition portions of storage base 28. This protects the containers from being tampered with or removed before ejector pinion 34 is unlocked for dispensing. After a container 52 is dispensed, as shown in Figure 12, the container 52 may be removed from strip 50 and the protruding portion of the strip 50 can be torn off at the edge 33 of wall 32 and discarded.

The operation of field unit 24 is under the control of a microprocessor. The microprocessor periodically unlocks a locking mechanism so that the user can manually dispense the next container in sequence. However, the operation is considerably more sophisticated than merely unlocking at predetermined intervals of

time. It can unlock based on a predetermined formula including predetermined intervals and also as a function of when actual dispensing has taken place. Therefore, it is important that the microprocessor know exactly when the user has dispensed a container.

Referring now to Figures 13-16, there are shown drawings of portions of the field unit 24 for annunciating that a dispensing operation has been completed and for preventing reverse rotation of ejector pinion 34.

Referring first to Figure 13, ejector pinion 34 is driven by a drive shaft 72 having cams 74 and 76 (Cam 74 is not fully visible in Figure 13). Drive shaft 72 is rigidly coupled to knob 36 which is rotated by the user to cause a dispensing operation. Cams 74 and 76 engage spring loaded switch actuators 78 and 80 which in turn operate ejector switches 82 and 84. Cams 74 and 76 each include two cam portions spaced 180° apart around drive shaft 72. They are oriented around shaft 72 so that closest portions of cams 74 and 76 are spaced 90° from one another around periphery of drive shaft 72 so that they will cause a closure of switches 82 and 84 at 90° intervals of the rotation of drive shaft 72. Figure 13 shows a position of drive shaft 72 whereat actuator 78 is engaged with cam 74 thereby turning switch 82 "on". As shown in Figure 13, at the time switch 82 is "on", actuator 80 is not engaged with cam 76 because cam 76 is out of position of drive shaft 72 so that it cannot be engaged. Therefore, actuator 80 is not engaged with cam 76 and switch 84 is therefore "off".

Figure 14 shows the same components as shown in Figure 13, but later in time, after drive shaft 72 has been rotated 90 degrees, so that cam 76 is engaged by actuator 80. As shown in Figure 14, when actuator 80 is engaged in cam 76, switch 84 turns "on". Cam 74 is then out of position so that actuator 78 cannot engage it. Therefore, switch 82 is "off".

Referring now to Figures 15 and 16, this process of signalling a complete dispensing operation is further illustrated.

Referring now to Figure 15, actuator 78 is shown engaged with cam 74, thereby causing switch 82 to be "on". This corresponds to the position shown in Figure 13. At the same time, actuator 80 is not engaged with cam 76 and therefore switch 84 is "off".

Figure 16 shows the same components as shown in Figure 15, but 1/4 rotation of drive shaft 72 later. Actuator 78 is not engaged with cam 74, but actuator 80 is engaged with cam 76. Therefore, switch 82 is off and switch 84 is "on". The "on" and "off" status of ejector switches 82 and 84 signal to the microprocessor when a dispensing operation is complete. This corresponds to completion of a 1/4 turn of drive shaft 72 rotation.

In addition, the shape of the cam depressions on drive shaft 72 are such that they prevent reverse shaft rotation when an actuator 78 or 80 is seated in its corresponding cam. The seating action is abrupt and concurrent only with a complete 90° drive shaft rotation to avoid ambiguous signalling. The microprocessor is programmed to electrically deactivate a switch 82

or 84 immediately after it has been mechanically activated. By using two switches that are alternately enabled and activated by a completed dispensing operation, erroneous multiple signals that could occur if only one switch were used are avoided.

The unlocking mechanism will be discussed with reference to Figures 17, 18 and 19. Ejector pinion 34 interacts with a locking wheel 86 which controls a locking wheel switch 88 for signalling the microprocessor as to the "locked" or "unlocked" status of field unit 24. As shown in Figure 17, locking wheel 86 includes a notched portion 90. The locking wheel 86 is positioned such that notched portion 90 can interact with locking pins 58 of ejector 34. Viewed from above, the locking wheel 86 is above that portion of ejector 34 including tips 70, as shown in Figures 18 and 19. Locking wheel 86 is rotated by interaction with locking pins 58 between those positions shown in figures 17 and 19. A rotary solenoid 212, not shown in this Figure, can reset the locking wheel 86 from its locked position in Figure 19 to its unlocked position in Figure 17.

As shown in Figure 18, a locking pin 58 of ejector pinion 34 engages notch 90 in locking wheel 86 and rotates the locking wheel 86 towards the "locked" position. Thus, rotating ejector pinion 34 during a dispensing operation, causes locking wheel 86 to change positions. Engagement of the next locking pin 58 with locking wheel 86, as shown in Figure 19, prevents further ejector pinion rotation. This automatically locks the dispensing device upon completion of a dispensing operation. Thus, Figure 19 illustrates a "locked"

position, resulting from the counter-clockwise rotation of locking wheel 86 as a result of clockwise rotation of ejector pinion 34. When it is time to unlock the dispensing device, the microprocessor actuates the solenoid to rotate locking wheel 86 backwards, i.e., clockwise, into the unlocked position, shown in Figure 17, thereby allowing the user to carry out the next dispensing operation.

Referring now to Figure 20, there is shown a view of locking wheel 86 coupled so as to be operated by a solenoid 212. A pulse from the microprocessor to solenoid 212 causes locking wheel 86 to rotate from the position shown in Figure 19 to the position shown in Figure 17.

Referring now to Figures 21 and 22, the container stop operation will be explained. Container stop pin 92 is mounted in a bottom plate 94 of field unit 24. Ejector pinion 34 includes notches 96 for clearing the stop pin during ejector pinion 34 rotation. In effect, stop pin 92 prevents further ejector pinion 34 rotation until the dispensed container 52 (shown in Figure 21) is removed. Thus, pin 92 prevents inadvertent or intentional attempted insertion of containers back into the unit which could jam the dispensing mechanism.

Referring now to Figure 23, there is shown a cross sectional view of field unit 24 in an assembled condition showing both dispensing module portion 46 and storage base 28. Slotted extension 40 of partition 30 is engaged by a cam lock 96 for securing dispensing module 46 and storage base 28 in an assembled condition. The electronic subsystem including the microprocessor

is formed on a circuit board 98 within dispensing module portion 46. The electronic subsystem is powered by a battery 200. A second battery 202 provides power for operating the solenoid. Circuit board 98 has mounted thereon a liquid crystal display 204 for displaying information to the user through a window 206 in the upper surface of dispenser module portion 46. Knob 36 for effecting a dispensing operation is shown in the upper right corner of this figure. Dispensing module portion 46 also includes a piezo electric alarm 208 for sounding an audible alarm through an opening 210 to alert the user that it is time to dispense a dose of medication.

Referring now to Figure 24, there is shown a view looking up into the dispenser module portion 46 of field unit 24. Ejector pinion 34 is not shown in this figure. Three conductor connector 216 provides interconnection to interface unit 22. Push button switch 214 allows the user to reset the microprocessor 100 to signal a base unit 20 request.

Field Unit 24 Electronic Subsystem

Referring now to FIGURES 25(A) and 25(B), there is shown a schematic diagram of the electronic subsystem hardware of a field unit 24. The functions of electronic subsystem are as follows:

1. It provides RAM (random access memory) for approximately 131 bytes (or more) of information. Fifty of these bytes correspond to 50 alphanumeric characters that define dosing schedule and identifying data. The remaining 81 bytes

of memory are used to store one byte which holds the dosage taken count and 80 bytes that contain the date and time data when up to forty dosages have been taken. The size of the RAM required is a function of the number of dosages that can be delivered and the amount of identifying data desired.

2. It provides information as to the real or related time of day and date. This information is made accessible to the microprocessor for the purposes of recording dosing times and for schedule checking.

3. It provides signalling element(s) to indicate to the microprocessor when a dosage has been dispensed.

4. A signalling element is provided to indicate that the ejector locking mechanism is in its locked position.

5. A communications path is provided for sending data to and receiving data from interface unit 22 and base unit 20.

6. A clock display with its associated driver circuitry is provided to display the next dosing time (including AM/PM and proper day indicators).

7. An ejector unlock mechanism and associated driver circuitry is provided such that access to dosages is under field unit electronics control.

8. An audible alarm with its associated circuitry is provided such that the monitor user can be alerted to an impending dosing time.

9. Programmable logic and control circuitry are provided for integrating the above eight functions into an effective unit.

These functions are carried out by the electronic subsystem which is microprocessor-based and under the control of software flow charted in FIGURE 26 and listed in Appendix I. The electronic subsystem features low power consumption such that it can operate from a single small battery for a period of time that will accommodate the longest possible dosing schedule that could be programmed into the unit. Solenoid 212 is powered by a separate solenoid battery 202 so that voltage swings due to solenoid operation will not affect electronic subsystems. Battery operation affords maximum portability and allows more convenient refrigeration, if required. The electronic subsystem has high noise immunity so that operation is not affected by spurious inputs, ambiguous data and address bus signal levels, or supply voltage fluctuations.

The electronics subsystem provides the above-listed functions and features in the following manner.

The programmable logic and control circuitry along with 112 bytes of RAM (random access memory) are provided by a Motorola MC146805E2 microprocessor unit 100, a NMC27C16 EPROM 102, a 74C00 address decode unit 104, and a 74HC373 Address Latch 106. The microcomputer supports the minimum volume requirement by including on one chip 112 bytes of user RAM, timer circuitry, 16 input/output lines, and the means to simulate a UART (universal asynchronous receiver/transmitter) communications interface to

the interface/base units. Of the 112 bytes of user RAM available, one byte contains the dosage taken count, 80 bytes are used to store up to 40 sets of delivered dosage date and time data, and the remaining 31 bytes are used for intermediate results and stack space. Up to 2048 bytes of program storage is provided by the UVEPROM (ultraviolet erased, electrically programmable, read-only memory). The 74C00 quad NAND gate decode unit and the 74HC373 latch allow the microprocessor to properly access the EPROM.

The timekeeping function is provided by the Motorola MC146818 real time clock plus RAM 108 and a 32.768 kHz crystal oscillator circuit 110. The real time clock retransmits the 32.768 kHz signal it receives from the crystal oscillator to supply the clock input the microcomputer requires. Crystal oscillator accuracy is approximately +/-.005% which amounts to an error of about 3 minutes in forty days, the maximum usage period as presently designed. Although the real time clock resolves time to the second, our present system only uses one minute resolution as this is more than sufficient precision for the immediate application. Another function of the real time clock is to, by means of its programmable alarm circuitry, supply a once-per-minute interrupt signal to the microcomputer's timer input where a once-per-minute timer interrupt is generated. System integration is supported by the 50 bytes of user RAM included in the real time clock. These 50 bytes of memory are used to store the identifying and dosing schedule data sent to the field unit during the monitor loading operation.

Microswitches 82, 84, operated by activators 78 and 80, respectively, riding on ejector drive shaft cams 74 and 76, provide the signalling means to indicate the delivery of the next dosage. The ejector drive shaft cams 74 and 76 and the microswitches' 82 and 84 orientation are such that the microswitches are alternately operated as dosages are sequentially delivered. By alternatively enabling the two microswitches 82, 84 electrically by means of output lines PA7 and PA6, a reliable indication of dosage delivery without danger of spurious, multiple signals is accomplished.

A locked ejector condition is signalled to the microcomputer by means of microswitch 88 activated by the ejector locking wheel and connected to input line, PA1.

Communications to the field unit are brought in on input line PA0, and data leaves the microcomputer through output line PA5 on its way to the interface and base units. Communication protocols are provided by UART programs in the EPROM. Baud rate generation is derived from the microcomputer clock frequency. Serial, rather than parallel, formats are used to simplify the communications interface and to permit the widest possible application to a variety of possible base units. The data format presently preferred is 110 baud rate, 8 bit word length, no parity bit, 1 stop bit, and XON/XOFF status disabled.

Liquid crystal display 204 with an ICM7211AM display driver 114 is used to provide next dosing time information to the user. Six output lines, PB0-PB5, are used to update the

driver and display after a dosage has been delivered.

Rotary solenoid 212 is used to release (unlock) the ejector locking mechanism under microcomputer control. A separate 4.2 volt battery 202 is used to energize the solenoid circuit since the large current draw causes voltage spikes that would interfere with proper microcomputer operation if a common battery were used. ULN2069 quad Darlington switches 112 provide a high current buffer for the microprocessor control line PB6.

The audible alarm function comprises a piezoelectric element 208 and driver circuitry 116. The driver circuit 116, including a transistor 118 and three resistors, serves to drive the piezoelectric element into oscillation, thereby producing an alarm.

Low power consumption is attained by using

1. All CMOS (complementary metal oxide silicon) circuitry.
2. A relatively slow clock rate (32.768 kHz).
3. Liquid crystal type clock display.
4. Piezoelectric type alarm element.

Consequently, a TR133 4.2 volt mercury battery 200 can power the entire circuit, exclusive of the solenoid, under worst case conditions, and for the maximum period of forty days and still retain a large reserve charge.

High noise immunity is attained by using:

1. All CMOS circuity with its wide noise margins and wide supply voltage limits.

2. Use of a separate battery for solenoid power.
3. Serial communications with error checking routines.

Minimum volume is attained by using:

1. Microcomputer on a chip. The MC146805E2 contains a microprocessor, 112 bytes of user RAM, timer, and 16 I/O lines, and can be programmed to perform the functions of an UART.
2. Multifunction real time clock. The MC146818 includes 50 bytes of RAM and an alarm interrupt.

Further integration and volume reduction is certainly possible through presently, or soon to be, available VLSI (very large scale integration) components that combine the microcomputer and real time clock functions, or the microcomputer and ROM functions, or even the microcomputer, ROM, and display driver functions. The ultimate in integration is also possible by means of customized CMOS gate arrays that could conceivably contain all the integrated circuit packages presently shown in our present design.

Field Unit Software

Referring now to FIGURE 26 there is shown a flowchart of the software associated with the FIGURE 25 hardware. A detailed program listing is set forth in Appendix I.

Program execution begins either after a power on reset (Step 300) (i.e. installation of a battery) or upon a hardware reset (Step 304) (i.e. pushing a reset switch 214) (see Figure 25A) A power on reset is not meaningful except that it

insures an orderly configuration of the microprocessor inputs and outputs immediately without the need of further operator action. After a power on reset, the program halts at a safe point (no outputs activated) and waits for the proper beginning of operation.

Normal program execution begins when the reset switch is pushed by the operator to signify a base unit request (see Step 304). This request may be either to load the field unit with data prior to use by the patient or it may be to have the field unit unload the data collected during the term of the patient's use of the Monitor. In either case the first action taken is to configure the microprocessor's input and output ports for proper operation. This routine is named "Reset" (Step 302).

Next, in the "Recogn" (recognition) routine (Step 306), the field unit first sends an ASCII "R" ("ready") to the base unit to indicate that communications may start and then waits to receive an ASCII character from the base unit in order to identify what function is being requested. If the received character is a "L", then the program jumps to the "Load" routine (Step 308). If the character is an "U", then the program jumps to the "Unload" routine (Step 310). If the character received is neither a "L" nor an "U", then a problem has occurred during communications and the program goes to the "Badcom" ("bad communication") section (Step 312).

The "Badcom" routine sends a "?" to the base unit to alert it to the communications problem and then the program jumps to "Wait" (Step

314) where it waits for another push of the reset button to restart the program.

When the field unit recognizes a base unit request to "Load", it proceeds to receive, echo, and store 50 bytes (characters and numbers) of data sent by the base unit. This data includes patient and study identifying information and the dosing parameters data. The information is received as ASCII coded characters that are echoed to the base unit to insure accurate data transfer and then stored in the real time clock user RAM area for later use. The "Load" routine also allows the operator to verify the proper operation of the field unit's alarm and unlock functions before placing the unit into service.

After loading is complete the program enters the "Start" routine (Step 316). Here the real time clock is set to the actual time and is configured to provide a once-a-minute timer interrupt to the microprocessor. Registers in the microprocessor are initialized, the liquid crystal clock display 204 is set to show the first scheduled dosing time and finally, the real time clock is started running. The program then goes to the "Minute" section (Step 318) where the field unit begins user related operations.

In the "Minute" routine, which is reached once per minute via a timer interrupt, the microprocessor first reads the real time clock and stores the present hours and minutes to compare against the events schedule. The following checks are made and appropriate action taken:

1. Is it midnight? If so, increment day counter.

2. Should the piezoalarm be activated? If so, sound alarm 4 times.
3. If the ejector should be unlocked and is not, a pulse is sent to the solenoid to reset the locking wheel.

After completing these tests, the program exists to the "Wait" routine.

For all but a few seconds each minute the program is idling in the "Wait" routine. While in this routine, the microprocessor is in its "Wait" operating mode which disables all functions except the ability to respond to interrupts and resets. This results in very low power consumption which allows the field unit to operate on a small battery for a period of at least 40 days. While in this state, the microprocessor performs no task and simply waits for one of three events to occur.

Once every minute the real time clock will initiate a microprocessor timer interrupt (Step 320) that causes the program to exit "Wait" and go to "Minute" where the alarm and unlock checks will be made as described above. Upon completion of the "Minute" functions, the program returns to "Wait" and awaits the next interrupt.

The delivery of a dosage and the accompanying activation of an ejector switch 82 or 84 (Step 322) will also cause the program to exit "Wait" by means of activating the microcomputer's external interrupt line. In this case the program jumps to "Dosage" (Step 316) where:

1. The dosage counter is incremented.
2. Date and time of dosage delivery data is stored in the microprocessor's user RAM.
3. The program jumps to "Minute" where the events schedule is checked.

After these tasks are completed the program once again returns to "Wait" to await the next interrupt or reset.

The third method of exiting "Wait" is the activation of the reset switch, signalling a base unit request. The servicing of a "Load" request was described above. An "Unload" request is now described.

At the end of the dosing period the field unit is returned to the doctor by the patient. The base unit program for field unit interrogation will request the operator to push the reset switch. The field unit program exits the "Wait" routine, passes through "Reset" to the "Recogn" section where the unload request is recognized, and then jumps to the "Unload" routine. This part of the program sends the original 50 bytes of identifying and dosing schedule data stored in the real time clock RAM back to the Base Unit. The 81 bytes of dosing data stored in the microprocessor's RAM are then sent to the base unit. The field unit checks for an accurate echo from the base unit after each data byte is sent. After data transmission is complete the field unit program goes back to "Wait". If any echo shows that a data transfer error has occurred, the "Unload" program is aborted and a jump is made to "Badcom" where an error flag is transmitted as described earlier.

Interface Unit

Referring now to FIGURE 27 there is shown a schematic diagram of interface unit 22 and the communication lines of base unit 20.

The purpose of the interface unit 22 is to provide signal level shifting such that the field unit can send and receive serial communications to and from any base unit 20 having an RS-232-C standard serial communications port. By means of this interface unit 22 the compliance monitor system then has the flexibility of using almost any computer with the proper software for its base unit 20 since the use of RS-232-C serial ports is so prevalent.

Under the EIA (Electronics Industries Association) RS-232-C standard, binary state 1 (one) signals are transmitted as a voltage between -5 and -15 volts. Binary state 0 (zero) signals are transmitted as a voltage between +5 and +15 volts. In the field unit the binary state 1 is at +4.2 volts and the binary state zero is at 0 volts ("ground"). Thus, the interface unit must be capable of converting the field unit's +4.2 volt transmissions into -5 to -15 volt signals, and must convert 0 volt levels into +5 to +15 volt signals for proper reception by the base unit RS-232-C port. Conversely, the -5 to -15 volt signals from the base unit port must be changed to approximately +4.2 volts, and +5 to +15 volt signals must be changed to 0 volts (ground) for use by the field unit. The base unit presently preferred (Radio Shack Model 100) outputs +/-5 volts on its RS-232-C transmission lines.

Interface unit 22 includes the following primary elements to provide the functions described above: a multi-voltage power supply including a power supply element 400, preferably a CALEX 22-120, a regulator 402, preferably a 7805, a RS-232-C line receiver 410, a RS-232-C line

driver 420, and connectors and cables to interconnect the base 20, interface 22, and field units 24. The power supply converts 120 volts AC input power into +12, -12, and +4.3 volts DC outputs for use by the line driver and receiver circuits. One fourth of a MC1488 Quad Line Driver takes 0 and +4.2 volts DC signals from the field unit's transmitting port (MC146805E2, pin 9, PA5) and converts them to +12 and -12 volts DC signals, respectively, for transmission to the base unit's receiving line (RXR, pin 3). One fourth of a MC1489 quad line receiver takes +5 and -5 volts DC signals from the base unit's transmitting line (TXR, pin 2), and converts them to 0 and +4.3 volts DC signals, respectively, for transmission to the field unit's receiving port (MC146805E2, pin 14, PA0).

The RS-232-C interface standard provides for up to 25 lines for control and data, but this system only requires use of three: line 2, TXR; line 3, RXR; and line 7, GND. Similarly, only three lines are needed between the interface unit and field unit.

The interface unit 22 circuitry does not necessarily need to be housed in a separate cabinet. These electronics could be contained in the field unit except for the disadvantages associated with the increased volume required for the electronics and the additional batteries needed to meet RS-232-C line voltage requirements. The interface electronics could also be contained in the base unit housing, especially since the required voltages are often already available. However, we presently separately house the interface electronics so that

other base units may be used without hardware modifications.

Base Unit Hardware

Referring now to FIGURE 28 there is shown a block diagram of base unit 20.

Base unit 20 provides the compliance monitor system user with a means of programming field units with the instructions necessary to control drug delivery and a means by which to retrieve data stored in the field unit at the end of the dosing program. Base unit 20 further provides a means for processing the recovered data and generating analytical reports detailing all system operations.

Base unit 20 is a computer system advantageously combining the following attributes:

1. ROM/RAM memory size sufficient to contain the LOAD-M and READ-M programs with their associated workspaces (approximately 12,500 bytes when written in BASIC) plus its own operating systems.
2. RS-232-C Serial communications interface -- for loading data to and unloading data from the interface/ field units.
3. Interface to a hard copy device -- usually a parallel printer port.
4. Display -- internal or external; CRT, LCD, etc. -- for prompting user.
5. Keyboard or other data entry device.
6. Hard copy unit -- usually a dot matrix printer capable of printing both text and graphics.

Other features of the base unit include:

1. A high level programming language (BASIC, FORTRAN, etc.) interpreter for ease of software development and revision.
2. BASIC interpreter in ROM -- eliminates the need for loading the system from, disk or tape before each operating session.
3. Sockets for application program ROMs -- eliminates the need for loading the application programs from disk or tape before each operating session; ROM does not require continuous battery backup; software is better protected from pirating.
4. Additional ROM/RAM memory space beyond the minimal requirement such that application programs for statistical analyses, protocol screening, etc. can reside in, and be run from, this one computer.
5. An on-board real time clock so that the operator need not repeatedly enter time and date information during field unit load and read operations.
6. A high level of system component integration -- for minimum space requirement, portability, battery operation, and lower cost.

The preferred embodiment uses a Radio Shack Model 100 portable computer 500 and an Epson RX-80 dot matrix graphics printer 510 to meet the above requirements. The Model 100 integrates all of the required functions, except that of the printer, plus several others into one very compact

and inexpensive unit. It contains 32K bytes of ROM where the BASIC interpreter resides. 32K bytes of RAM are available, part of which may hold the LOAD-M and READ-M application programs. This RAM is backed-up by a NICAD battery which retains the programs in memory indefinitely when the AC adapter is used or for several days when the unit is operated from batteries. Future versions of the base unit will have the application programs stored in a second 32K byte ROM for which there is a socket in the bottom of the computer. The programs could then never be lost due to loss of battery charge. Further, when programs are in ROM, they are stored in machine language or tokenized BASIC, thus affording better software security.

The Model 100's input/output ports include a parallel printer port for sending output to the dot matrix printer and a RS-232-C serial communications port for communicating with the interface/field units and, perhaps, with other computers. The serial port operates at several user-selectable baud rates including the relatively slow 110 baud rate. This rate is still fast enough to provide a convenient data transfer rate while slow enough to allow the use of a battery conserving, slower clock frequency in the field unit.

Other I/O ports available, but not presently used, are a bar code wand input, a cassette recorder interface, and a telephone modem. A bar code wand could be used with future models to take inventories required for drug control. The cassette recorder port provides a means for reloading the application programs into

memory if memory backup power is ever lost. The modem might be used to allow future field and base units to communicate remotely over phone lines.

The Model 100 has an on-board real time clock so that time and date information need be inputted or updated only infrequently.

The display function is provided by an internal 40 character by 8 line liquid crystal dot graphics display. Prompts and data may be presented in any combination of text and graphics.

The typewriter style keyboard includes cursor control and function keys for easy data entry and program selection.

The Epson RX-80 dot matrix graphics printer has both text and graphics print modes and uses 8½ x 11" continuous forms. Data and instructions from the Model 100 are handled by a standard Centronics compatible, 8-bit parallel interface.

Of course, many other computer and peripheral combinations could provide the required base unit functions. The Model 100 and RX-80 units were chosen because they offered the best combination of features and low cost then available. Another method of reducing system cost would be to provide software packages for several common computer systems that meet base unit requirements. The customer then would be able to make use of already existing computer hardware.

Base Unit Load Software

Referring now to FIGURE 29 there is shown a flowchart of the base unit "LOAD-M" software for storing a medication schedule into a field unit

24. A detailed program listing is set forth in Appendix II.

The LOAD-M program is selected by moving the main menu cursor over LOAD-M and pressing the "Enter" key. The program starts automatically and prompts the user through all loading operations. Even the most inexperienced operator should be capable of reliable data entry after only minimal training. Proper format checks and escape sequences prevent and correct most erroneous inputs.

LOAD-M is selected after field unit 24 has been loaded with dosages and before being given to the patient. The program collects the study and patient identifying data and the dosage schedule and control data through keyboard responses to instructions prompted on the liquid crystal display. This data is loaded into the field unit by way of the interface unit. Finally, a hard copy report of the loaded data is printed.

More specifically, operation is as follows:

1. MMS Logo, Copyright Notice, and "Monitor Loading Routine" Displayed.

2. Data Entry - Identifying and schedule data are entered.

a. Study ID# - 1 to 6 alphanumeric characters. If more than six characters are entered, only the first six are used. Other formats could be used.

b. Patient ID# - 1 to 6 alphanumeric characters. If more than six characters are entered, only the first six are used. Other formats could be used.

c. Daily dosing schedule - 1 to 4 "on the hour" dosing times. Each selected time must be no earlier than the previous dosing time. Selection is made by moving the cursor over the desired hour and pressing "Enter". Once four times are entered, the program automatically jumps to the next operation. An "entry complete" input is required when less than 4 dosing times are entered.

d. First Dosage Time - The selected dosage schedule is displayed on the LCD screen and the starting dosage is chosen by moving the cursor over the desired time and pressing "Enter".

e. Starting Day Offset - If dosage taking is not to begin before the end of the current day, the number of days before dosages are to be taken should be entered. This feature allows the monitor system operator to load field units in advance, whenever convenient.

f. Number of Doses Loaded - Knowing the number of doses loaded allows field unit 24 to stop alarm and display functions after the last dose is delivered.

g. Monitor Serial # - 1 to 6 alphanumeric characters. If more than six characters are entered, only the first six are used. An "L" in the first position indicates that the field unit being loaded has the computer controlled unlock feature and that the unlock period must be inputted. Other formats could be used.

g. Unlock Period - The operator chooses one of four unlock periods (2 min., 30 min., 59 min., or "Always") by moving the cursor over the proper label and pressing "Enter". In operation, the field unit will unlock the ejector mechanism before the scheduled dosing time by the amount of time specified by the unlock period. Other periods could be used.

h. Alarm Start - The operator chooses one of four alarm start periods (2 min., 15 min., 30 min., or "None") by moving the cursor over the proper label and pressing "Enter". In operation, the field unit will start sounding the reminder alarm four times every minute when the actual time is within the alarm start period before the scheduled dosing time. Other periods could be used.

i. Time/Date Check - The computer will display the time and date as given by its own real time clock. If either time or date is in error, the operator may easily correct them at this time by entering the correct values using the formats shown.

Note: Data formats other than those shown above (i.e. longer or shorter serial numbers; fewer, more, or different unlock and alarm start periods; different dosage scheduling options; etc.) can be used as long as the field unit has sufficient RAM capacity and is programmed to

interpret a different set of schedule parameters.

3. Field Unit Loading/Testing - Entered data is moved into field unit.

a. First, LOAD-M disassembles and converts the entered string values into 50 bytes of data suitable for transmission to and use by the field unit.

b. The operator is then prompted to connect the interface unit (which is connected to the base unit at the RS-232-C port) to the field unit. When the field unit's reset switch is pushed the base unit and field unit begin communications. The entire loading operation is automatic and needs no operator intervention. The LOAD-M program signals to the field unit that a load operation is beginning, waits for a "Ready" reply, and then sends the 50 bytes of data in a sequence expected by the field unit. After each byte is sent, the base unit checks that the field unit has echoed the proper data indicating good data transmission. If a bad echo is received, the data transfer is aborted and restarted.

c. After loading is complete, the operator is prompted to check alarm and unlock features of the field unit if so desired. By pressing "B" the alarm should sound. By pressing "U" the unlock solenoid should activate.

d. When loading and testing are complete, LOAD-M prompts the operator to turn off and disconnect the interface unit, and ready the printer.

4. Print Permanent Record of the Loading Operation.

a. The program proceeds to automatically print a one page record of the loading operation (see sample in Appendix II). All inputted data is repeated and the time and date of loading is recorded. This record then serves to document the loading phase of the monitoring program for use in the patient's, program, and physician's files.

5. Program Exit.

a. The operator is asked whether there is another field unit to be loaded. If so, the program jumps to the beginning (just after the logo and copyright notice) to restart. If there are no more field units to load, LOAD-M is exited and program control returns to the Model 100 main menu where another program may be selected if desired.

Note: The LOAD-M operations require only approximately two minutes to complete (per field unit).

Base Unit Read Software

Referring now to FIGURE 30 there is shown a flowchart of the base unit "READ-M" software for

debriefing a field unit 24 and preparing a compliance report. A detailed program listing and a sample compliance report are set forth in Appendix III.

The READ-M program is selected by moving the main menu cursor over READ-M and pressing the "Enter" key. The program starts automatically and prompts the user through all unloading operations. Even the most inexperienced operator should be capable of debriefing field units after only minimal training.

READ-M is selected after the patient returns the field unit at the end of the dosing program. The program unloads from the field unit, by way of the interface unit, the dosage delivery data as well as the previously loaded identification and schedule control data. The data is analyzed, presented on the LCD, and printed on a one or two page report. The format of the LCD and hard copy reports is such that the level of compliance is evident at a glance.

More specifically, operation is as follows:

1. MMS Logo, Copyright Notice, and "Monitor Debriefing Routine" are displayed.

2. Unload Field Unit - Stored data is moved into base unit.

   a. Operator is prompted to connect the interface unit (which is connected to the base unit at the RS-232-C port) to the field unit, turn on the interface unit, and press the field unit's reset switch.

   b. After the reset switch is pressed, the base unit and field unit begin

communications through the interface unit. The entire unloading operation is automatic and needs no operator intervention. The READ-M program awaits a "Ready" signal from the field unit, then signals that an unload operation is beginning. Having established communications, the field unit sends 131 bytes of data to the base unit. The first 50 bytes are the same data originally stored during the load operation. The 51st byte sent contains the count of dosages taken. The final 80 bytes, arranged as 40 pairs, are compressed representations of the dosage delivery time and date data. If all 40 dosages were not taken, data pairs beyond the dosages taken point contain meaningless data. After each data byte is received by the base unit, it is echoed to the field unit to verify proper data transfer. If the field unit receives a bad echo, it sends an ASCII '?" to the base unit which causes the READ-M program to restart the unload operation.

3. Assemble Identifying and Schedule Data.

a. The first 50 bytes received are assembled into the proper string and numeric variables that represent the schedule and identifying data originally loaded into the field unit by the LOAD-M program.

4. Display Compliance Report.

a. The READ-M program next unpacks the dosage delivery data and presents an analysis of the compliance levels along with the identifying and schedule data on the liquid crystal display. Compliance is shown by plotting the dosage number against the actual dosing time error. The five error levels used are:

- More than 2 hours early
- Less than 2 hours early
- Within plus or minus one hour
- Less than 2 hours late
- More than 2 hours late

An asterisk is plotted at the appropriate error level for each of the dosages taken.

5. Print Hard Copy of the Compliance Report.

a. The compliance report described in 4 is output to the printer. However, instead of plotting an asterisk, the actual dosing time in hours and minutes is plotted at the appropriate error level for each of the dosages taken. Additionally, if the actual dosing time is not on the proper day, the number of days early or late is printed after the dosing time. The hard copy report will require one or two pages depending upon the number of dosages taken. This record then serves to document the

debriefing phase of the monitoring program for use in the patient's, program, and physician's files.

Note: Other methods of presenting the compliance analysis (e.g. using four hour error bands, statistical analyses, etc.) are equally valid. The READ-M program quickly shows compliance levels "at-a-glance" and assumes that more detailed analyses can be made in other programs.

6. Program Exit.

a. The operator is asked whether there is another field unit to be unloaded. If so, the program jumps to the beginning (just after the logo and copyright notice) to restart. If there are no other field units to unload, READ-M is exited and program control returns to the Model 100 main menu where another program may be selected if desired.

Note: The READ-M operations require only approximately two minutes to complete (per field unit).

Further Enhancements

- Additional base unit software can be provided for patient screening per the drug therapy protocol during the loading operation in medication efficacy studies.

- Additional base unit software can be provided to do statistical analyses of the compliance data for one or more patients.

- By means of a keyboard or card reader one field unit could keep track of dosage delivery to several patients by requiring the entry of access and identifying codes.

- A modem contained within, or attached to, the field unit would allow remote uploading of data to the base unit from the field unit and downloading of new instructions to the field unit from the base unit.

While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims which scope is to be accorded the broadest interpretation so as to encompass all such modifications and equivalent structures.

CONTROLLED DISPENSING DEVICE
FIELD UNIT PROGRAM LISTING

APPENDIX I

MONITOR5.TXT
REV. 07
08.22.84.LEP

```
CLOCKS: 32.768 kHz (F1) INTO 146818 FROM CRYSTAL OSCILLATOR
        32.768 kHz (F2) (F1/1) INTO 146805E2 FROM 146818
        6553.6 Hz  (F3) (F2/5) BUS FREQUENCY

    BUS CYCLE PERIOD = .000152588 SEC. (1/F3)

    FOR 110 BAUD:
       # TOTAL CYCLES / BIT PERIOD = 60 = 59.57818 = 6553.6/110
                                          (.7% ERROR)

PORT ASSIGNMENTS: PORT A: 0000
                  DDRA  : 0004   00 UPON RESET
                                 FC UPON INITIALIZATION
    BIT 0 = IN(0)  = RS-232C INTO MONITOR (FROM LINE 2,TXR)
                     MARK(-12v)=1(+4.3v)  SPACE(+12v)=0(GND)
                     SET MODEL 100 FOR 28N1D
        1 = IN(0)  = SPROCKET LOCK STATUS SWITCH
                     HIGH = LOCKED   LOW = UNLOCKED
        2 = OUT(1) = DEBUG USE ONLY (GREEN LED - `MINUTE')
        3 = OUT(1) = DEBUG USE ONLY (RED LED-`WAIT'&`DOSAGE')
        4 = OUT(1) = SOLENOID - UNLOCK
        5 = OUT(1) = RS-232C OUT OF MONITOR (TO LINE 3, RXR)
                     1(+4.3v)=MARK(-12v)  0(GND)=SPACE(+12v)
                     SET MODEL 100 FOR 28N1D
        6 = OUT(1) = MICROSWITCH #2 - DRUG DELIVERED
        7 = OUT(1) = MICROSWITCH #1 - DRUG DELIVERED
```

PORT B: 0001

DDRB : 0005 00 UPON RESET

FF UPON INITIALIZATION

BIT 0 = OUT(1) = LCD DATA, B0

1 = OUT(1) = LCD DATA, B1

2 = OUT(1) = LCD DATA, B2

3 = OUT(1) = LCD DATA, B3

4 = OUT(1) = LCD DIGIT SELECT, DS1

5 = OUT(1) = LCD DIGIT SELECT, DS2

6 = OUT(1) = LCD CHIP SELECTS

7 = OUT(1) = PIEZO ALARM

146818 REGISTERS:

REGISTER A($010A) - 00101010 = 2A = 32.768 kHz CRYSTAL
15.625 mSec PI
64 Hz SQW (NOT USED)

BIT 0 - 3 RATE SELECT (0000 = 15.625 mSec PI,
64 Hz SQW)

4 - 6 DIVIDER BITS (010 = 32.768 kHz CRYSTAL)

7 UPDATE IN PROGRESS FLAG (READ ONLY)

REGISTER B($010B) - 00100110 = 26 = RUN, PIE DISABLED,
AIE ENABLED, UIE DISABLED,
SQWE DISABLED, BINARY,24,
NO DSE

SET BIT 7(HOLD)($A6) DURING TIME INITIALIZE

BIT 0 - DAYLIGHT SAVINGS ENABLE (0=DISABLE)
1 - 24/12 HOUR FORMAT (1=24)
2 - DATA MODE (1=BINARY)
3 - SQW ENABLE (0=DISABLE)
4 - UPDATE ENDED INTERRUPT ENABLE (0=DISABLE)
5 - ALARM INTERRUPT ENABLE (1=ENABLE)
6 - PERIODIC INTERRUPT ENABLE (0=DISABLE)
7 - SET (1=HOLD 0=RUN)

REGISTER C(010C) - READ ONLY (CLEARED BY A READ)
BIT 6 - PERIODIC INTERRUPT FLAG
5 - ALARM INTERRUPT FLAG

REGISTER D(010D) - READ ONLY (NOT USED)

146818 RAM: 0100 SECONDS
0101 SECONDS ALARM
0102 MINUTES
0103 MINUTES ALARM
0104 HOURS
0105 HOURS ALARM
0106 DAY OF WEEK
0107 DATE OF MONTH
0108 MONTH
0109 YEAR
010A REGISTER A
010B REGISTER B
010C REGISTER C
010D REGISTER D

(USER RAM) (ALL DATA IS ASCII)

(NUMERIC VALUES ARE REPRESENTED BY ASCII EQUIVALENT)

```
010E  D$(0)  SI$ LEFT ]
010F  D$(1)  SI$ ]
0110  D$(2)  SI$ ]
0111  D$(3)  SI$ } STUDY ID#
0112  D$(4)  SI$ ]
0113  D$(5)  SI$ RIGHT]
0114  D$(6)  PI$ LEFT ]
0115  D$(7)  PI$ ]
0116  D$(8)  PI$ ]
0117  D$(9)  PI$ } PATIENT ID#
0118  D$(10) PI$ ]
0119  D$(11) PI$ RIGHT]
011A  D$(12) SN, # OF DOSAGES/DAY, 1-4
011B  D$(13) SC(0) SCHEDULED DOSING HOUR (TARGET HOUR) (0-23)
011C  D$(14) SC(1)
011D  D$(15) SC(2)
011E  D$(16) SC(3)
011F  D$(17) D1, FIRST DOSAGE POINTER, 0-3
0120  D$(18) SN$ LEFT ]
0121  D$(19) SN$ ]
0122  D$(20) SN$ ]
0123  D$(21) SN$ } MONITOR SERIAL#
0124  D$(22) SN$ ]
0125  D$(23) SN$ RIGHT]
0126  D$(24) UP, UNLOCK PERIOD (58,30,01, OR 61)
0127  D$(25) AP, ALARM PERIOD (58,45,30, OR 61)
0128  D$(26) DA$ LEFT ]
0129  D$(27) DA$ ]
```

```
012A  D$(28) DA$ ]
012B  D$(29) DA$ ]
012C  D$(30) DA$ } LOADING DATE
012D  D$(31) DA$ ]
012E  D$(32) DA$ ]
012F  D$(33) DA$ RIGHT]
0130  D$(34) TM$ LEFT ]
0131  D$(35) TM$ ]
0132  D$(36) TM$ ]
0133  D$(37) TM$ ]
0134  D$(38) TM$ } LOADING TIME
0135  D$(39) TM$ ]
0136  D$(40) TM$ ]
0137  D$(41) TM$ RIGHT]
0138  D$(42) STARTING MINUTES (26 GOES TO 27 IN LOAD-M)
0139  D$(43) STARTING HOURS
013A  D$(44) SD, STARTING DAY OFFSET
013B  D$(45) TD, TOTAL # OF DOSAGES, 1 - 40 (26-27 IN LOAD-M)
013C  D$(46) 0 (NOT USED)
013D  D$(47) 0 (NOT USED)
013E  D$(48) 0 (NOT USED)
013F  D$(49) 0 (NOT USED)
```

146805 RAM MAP:

0000	PORT A	PORT A DATA REGISTER
0001	PORT B	PORT B DATA REGISTER
0002		EXTERNAL MEMORY SPACE
0003		EXTERNAL MEMORY SPACE
0004	DDRA	PORT A DATA DIRECTION REGISTER
0005	DDRB	PORT B DATA DIRECTION REGISTER
0006		EXTERNAL MEMORY SPACE
0007		EXTERNAL MEMORY SPACE
0008	TIDATA	TIMER DATA REGISTER
0009	TCR	TIMER CONTROL REGISTER

TCR7 - INTERRUPT REQUEST (CLEARED BY RESET)
TCR6 - INTERRUPT MASK (1=MASKED)
TCR5 - EXTERNAL CLOCK SOURCE (1=EXTERNAL)
TCR4 - EXTERNAL TIMER PIN ENABLED (1=ENABLE)
TCR3 - PRESCALER RESET TO 0 WITH A 1
TCR2 - TCR0 - DIVIDE BY FACTOR (000= /1)

0010	ATEMP	TEMPORARY STORAGE OF A TEMP. STORAGE OF DAY OF WEEK DATA FROM RTC READ
0011	CHAR	CHARACTER BYTE FOR SEND C RECEIVED CHARACTER ASSEMBLY BYTE IN REC C @HOUR2 - 1
0012	COUNT	BIT COUNTER FOR SEND C & REC C
0013	XTEMP	TEMPORARY STORAGE OF X
0014	@HOUR	TARGET HOUR (0-23)
0015	NEXTHR	NEXT HOUR POINTER, 0-3
0016	DAYCNT	ACTUAL DAY COUNTER (# RTC DAY OF WEEK CHANGES)
0017	@DAY	TARGET DAY COUNTER (# OF NEXTHR WRAP-AROUNDS)
0018	HOURS	ACTUAL HOURS DATA REGISTER - FROM RTC READ
0019	MINUTS	ACTUAL MINUTES DATA REGISTER - FROM RTC READ
001A	DAYWEK	DAY OF WEEK REFERENCE
001B	@HOUR2	UPCOMING TARGET HOUR
001C	DOSTKN	D$(50), # OF DOSES DELIVERED
001D-006D		D$(51)-D$(131), TIME AND DAY STORAGE (80 BYTES)
006E-007F		STACK (17 BYTES)

146805 ROM MAP:

MAIN ROUTINES:

1800	RESET	UPON MONITOR RESET BY PUSHBUTTON SWITCH OR POWER UP
1820	RECOGN	'READY', LOAD OR UNLOAD, 'ERROR'
1840	LOAD	READS DATA FROM BASE UNIT INTO MONITOR
18A0	START	INITIALIZES AND STARTS RTC
1900	UNLOAD	SENDS DATA FROM MONITOR TO BASE UNIT
1A00	WAIT	POWER DOWN & WAIT FOR INTERRUPT OR RESET
1B00	MINUTE	TIMER (RTC ALARM) INTERRUPT SERVICE ROUTINE (1/MIN)
1D00	DOSAGE	EXTERNAL INTERRUPT (DOSAGE DELIVERED) ROUTINE

SUBROUTINES:

```
1E00  SEND C  SERIAL OUTPUT TO INTERFACE UNIT
                 CHARACTER MUST BE IN REG A BEFORE
                    ENTERING ROUTINE
              REG A IS ALTERED
              CHARACTER IS IN 0010 (`ATEMP') AT END
              110 BAUD, START, 8 DATA, NO PARITY, 1 STOP
              SET MODEL 100 FOR 28N1D

1E30  DELAY   30 CYCLE DELAY FOR SERIAL COMMUNICATIONS
              ROUTINES
              CALLED BY `SEND C' AND `REC C'
              X IS ALTERED IF `DELAY' NOT USED IN REC C
                 OR SEND C

1E40  REC C   SERIAL INPUT FROM INTERFACE UNIT
              RECEIVED CHARACTER GOES INTO REG A
              REG A IS ALTERED
              110 BAUD, START, 8 DATA, NO PARITY, 1 STOP
              SET MODEL 100 FOR 28N1D

1E80  BADCOM  BAD COMMUNICATION - SENDS `?' AND WAITS

1E90  UNLOCK  UNLOCK SOLENOID ON FOR 50 mSec (IF LOCKED)

1EA2  BELL    PIEZO ALARM ON FOR 100 mSec/ OFF FOR 500 mSec

1EC0  ADVTGT  TARGET REGISTERS & LCD UPDATE TO NEXT
                 DOSING HOUR
```

SUBROUTINES (continued):

1F20 LCDOUT LOAD A DISPLAY DIGIT

1F30 RTCRED READ RTC HOURS, MINUTES, & DAY OF WEEK

1F50 PACK PACK/STORE HR, MIN & RAM DAY DATA INTO 2 BYTES OF 146805 USER RAM

1F80 DASH PUT DASH IN HOUR DISPLAY

INTERRUPT VECTORS:

1FF6-1FF7	TIMER INTERRUPT FROM WAIT	- 1B00 ('MINUTE')
1FF8-1FF9	TIMER INTERRUPT	- 1B00 ('MINUTE')
1FFA-1FFB	EXTERNAL INTERRUPT	- 1D00 ('DOSAGE')
1FFC-1FFD	SWI	- 1B00 ('MINUTE')
1FFE-1FFF	RESET	- 1800 ('RESET')

MAIN ROUTINES:

```
                                (RESET SWITCH)
                              (146805 PORT SET-UP)
1000 1800   RESET   A6FC   LDA   #$FC   INITIALIZE 146805E2
1002 1802           B704   STA   0004     PORT A DDR SET, PA0
                                            & PA1 INPUTS

1004 1804           A6FF   LDA   #$FF
1006 1806           B705   STA   0005     PORT B DDR SET,
                                            ALL OUTPUTS

1008 1808           A6E3   LDA   #$E3
100A 180A           B700   STA   0000     PORT A OUTPUTS
                                            INACTIVE

100C 180C           A640   LDA   #$40
100E 180E           B701   STA   0001     PORT B OUTPUTS
                                            TURNED OFF

1010 1810           CC1820 JMP   RECOGN
                    [19]
```

NOTE: 146818 DOES NOT NEED TO BE INITIALIZED AT THIS POINT
ALTHOUGH NOT KEEPING CORRECT TIME, IT IS PROVIDING
PROPER F2 (32.768 kHz) SIGNAL INTO 146805 FOR
ACCURATE 110 BAUD TIMING
UPON RESET: PIE;AIE,UIE,SQWE ARE CLEARED
IRQF,PF,AF,UF ARE CLEARED

```
                        (LOAD/UNLOAD RECOGNITION)
     1020 1820   RECOGN  A652   LDA   #$52
     1022 1822           CD1E00 JSR   SEND C  SENDS `R'($52)
                                        FOR `READY'

 5   1025 1825           CD1E40 JSR   REC C   WAITING TO RECEIVE `L'
                                              OR `U'
     1028 1828           A155   CMP   #$55    CHECK FOR `U' (UNLOAD)
     102A 182A           2603   BNE   RECOG1
     102C 182C           CC1900 JMP   UNLOAD

10   102F 182F   RECOG1  A14C   CMP   #&4C    CHECK FOR `L' (LOAD)
     1031 1831           2603   BNE   RECOG2
     1033 1833           CC1840 JMP   LOAD

     1036 1836   RECOG2  CC1E80 JMP   BADCOM  TO `BAD COMMUNICATION'
                                          IF NOT `U', `L'
15                       [25]
     ------------------------------------------------------------

                        (LOAD DATA FROM BASE UNIT)
     1040 1840   LOAD    A64C   LDA   #$4C
     1042 1842           CD1E00 JSR   SEND C  SEND `L' (LOAD ECHO)

     1045 1845   LOAD1   CD1E40 JSR   REC C   WAITING TO RECEIVE
                                              `C'(CONTINUE)
20   1048 1848           A143   CMP   #$43    CHECK FOR `C'
     104A 184A           26F9   BNE   LOAD1   LOOP UNTIL `C'

     104C 184C           A652   LDA   #$52
     104E 184E           CD1E00 JSR   SEND C  SEND `R' (READY)
                         ------------------------------------
```

```
                        (RECEIVE/STORE/ECHO LOOP)
     1051 1851          5F      CLR   X
     1052 1852  LOAD2   CD1E40  JSR   REC C    WAITING FOR DATA
     1055 1855          D7010E  STA   X,010E   WRITE DATA INTO RTC
                                                 RAM STARTING AT 010E
     1058 1858          4F      CLR   A
     1059 1859          D6010E  LDA   X,010E   RELOAD A FROM RTC FOR
     ECHO
     105C 185C          CD1E00  JSR   SEND C   ECHO
     105F 185F          5C      INC   X        INCREMENT RTC MEMORY
                                                 POINTER
     1060 1860          A332    CPX   #$32     CHECK FOR END OF FILE
                                                 (50 ITEMS)
     1062 1862          26EE    BNE   LOAD2    LOOP FOR NEXT DATA
     ------------------------------------------------------------

                      BELL TEST - SOLENOID TEST)
     1064 1864  LOAD4   CD1E40  JSR   REC C    WAITING FOR `C' OR `B'
                                                 OR `U'
     1067 1867          A143    CMP   #$43     CHECK FOR `C'
                                                 (COMPLETE)
     1069 1869          2712    BEQ   LOAD3

     106B 186B          A142    CMP   #$42     CHECK FOR `B' (BELL)
     106D 186D          2605    BNE   LOAD5
     106F 186F          CD1EA2  JSR   BELL     RING BELL
     1072 1872          20F0    BRA   LOAD4

     1074 1874  LOAD5   A155    CMP   #$55     CHECK FOR `U' (UNLOCK)
     1076 1876          26EC    BNE   LOAD4
     1078 1878          CD1E90  JSR   UNLOCK   PULSE UNLOCK SOLENOID
     107B 187B          20E7    BRA   LOAD4
     ------------------------------------------------------------
```

```
     107D 187D   LOAD3   A646   LDA   #$46
     107F 187F            CD1E00 JSR   SEND C  SEND `F' TO
                                               ACKNOWLEDGE FINISH
     1082 1882            CC18A0 JMP   START
5                         [69]
     ------------------------------------------------------------

                          (INITIALIZE 146818 RTC)
     10A0 18A0   START    A6A6   LDA   #$A6
     10A2 18A2            C7010B STA   010B    RTC PUT ON HOLD DURING
                                                  TIME SET
10   10A5 18A5            4F     CLR   A
     10A6 18A6            C70100 STA   0100    SECONDS SET TO 00
     10A9 18A9            A63B   LDA   #59
     10AB 18AB            C70101 STA   0101    SECONDS ALARM SET FOR
                                                  59
15   10AE 18AE            A6FF   LDA   #$FF    DONT CARE CODE
     10B0 18B0            C70103 STA   0103    MINUTES ALARM SET
     10B3 18B3            C70105 STA   0105    HOURS ALARM SET
     10B6 18B6            A62A   LDA   #$2A    SET RTC REGISTER A
     10B8 18B8            C7010A STA   010A    32.768 kHz,15.625 mSec
20                                                PI,64 Hz SQW
     10BB 18BB            C60138 LDA   0138    READ STARTING MINUTES
     10BE 18BE            C70102 STA   0102    STARTING MINUTES MOVED
                                                  INTO 0102
     10C1 18C1            C60139 LDA   0139    READ STARTING HOURS
25   10C4 18C4            C70104 STA   0104    STARTING HOURS MOVED
                                                  INTO 0104
     10C7 18C7            A607   LDA   #7
     10C9 18C9            C70106 STA   0106    DAY OF WEEK SET TO 7
     ------------------------------------------------------------
```

```
                    (INITIALIZE 146805 RAM REGISTERS)
     10CC 18CC          B71A   STA   DAYWEK  DAY OF WEEK REFERENCE
                                              SET TO 7
     10CE 18CE          C6011F LDA   011F    D1
     10D1 18D1          B715   STA   NEXTHR  FIRST DOSAGE POINTER
                                              INTO NEXTHR
     10D3 18D3          3F16   CLR   DAYCNT
     10D5 18D5          3C16   INC   DAYCNT  ACTUAL DAY COUNTER SET
                                              TO 1
     10D7 18D7          C6013A LDA   013A
     10DA 18DA          B717   STA   @DAY
     10DC 18DC          3C17   INC   @DAY    LOAD TARGET DAY WITH
                                              OFFSET + 1
     10DE 18DE          3F1C   CLR   DOSTKN  CLEAR DOSES TAKEN
                                              COUNTER

     10E0 18E0          1F00   BCLR7 PA7     ENABLE MICROSWITCH #1
     ------------------------------------------------------------

                (INITIALIZE @HOUR & @HOUR2 & SET CLOCK)
     10E2 18E2          CD1ECD JSR   ADVTG1  SET 1st DOSE TIME INTO
                                              DISPLAY
     ------------------------------------------------------------

                         (CLEAR DOSAGE MEMORY)
     10E5 18E5          5F     CLR   ACCX
     10E6 18E6  START1  6F1D   CLR   001D,X  CLEAR 80 BYTES
                                              STARTING @ 001D
     10E8 18E8          5C     INC   ACCX    PREVENTS ACCIDENTAL
                                              $1A (26) IN
     10E9 18E9          A350   CPX   #80     UNUSED BYTES
     10EB 18EB          26F9   BNE   START1
     ------------------------------------------------------------
```

```
                    (146805 TIMER SETUP)
    10ED 18ED       A630   LDA  $30    SET UP TIMER CONTROL
                                        REGISTER
    10EF 18EF       B709   STA  TCR    TCR7 - INTERRUPT
                                        REQUEST CLEARED
                                        TCR6 - INTERRUPT MASK
                                        CLEARED
                                        TCR5 - EXTERNAL CLOCK
                                        SOURCE
                                        TCR4 - EXTERNAL TIMER
                                        PIN ENAB.
                                        TCR3 - PRESCALER NOT
                                        RESET TO 0
                                        TCR2 - TCR0 DIVIDE BY 1
    ------------------------------------------------------

                        (LET RTC RUN)
    10F1 18F1       C6010C LDA  010C    READING REGISTER C
                                        CLEARS ALARM FLAG
    10F4 18F4       A626   LDA  #$26    SET RTC REGISTER B
    10F6 18FE       C7010B STA  010B    RUN, AIE ON, PIE, UIE,
                                        SQWE OFF BINARY,
                                        24, NO DSE
    ------------------------------------------------------

    10F9 18F9       CC1B00 JMP  MINUTE  GO TO `MINUTE' TO SET
                                        BELL & UNLOCK
                    -----
                    [   ]
    ------------------------------------------------------
```

```
                    (UNLOAD DATA TO BASE UNIT)
                    (HANDSHAKE COMMUNICATIONS)
1100 1900  UNLOAD  A655   LDA   $55
1102 1902          CD1E00 JSR   SEND C  SEND `U' (UNLOAD
                                          ECHO)

1105 1905  ULOAD1  CD1E40 JSR   REC C   WAITING TO RECEIVE
                                          `C'(CONTINUE)
1108 1908          A143   CMP   43      CHECK FOR `C'
110A 190A          26F9   BNE   ULOAD1  LOOP UNTIL `C'
```

```
              (146818 USER RAM UNLOAD/ECHO CHECK LOOP)
110C 190C          5F     CLR   X

110D 190D  ULOAD2  D6010E LDA   010E,X  MOVE CHARACTER FROM
                                          RTC RAM INTO A
1110 1910          AD12   BSR   ULOAD6
1112 1912          5C     INC   X       INCREMENT DATA COUNTER
1113 1913          A332   CPX   50
1115 1915          26F6   BNE   ULOAD2  REPEAT LOOP UNTIL
                                          50 BYTES
```

(146805 UNLOAD/ECHO CHECK LOOP)

```
          1117 1917           5F     CLR   X

          1118 1918  ULOAD4   E61C   LDA   001C,X  LOAD DOSAGE DELIVERY
                                                     DATA
          111A 191A           AD08   BSR   ULOAD6  SEND DATA & CHECK
                                                     ECHO
          111C 191C           5C     INC   X        INCREMENT DATA
                                                     COUNTER
          111D 191D           A351   CMP   #81      TEST FOR 81 BYTES
                                                     SENT
          111F 191F           26F7   BNE   ULOAD4   REPEAT LOOP UNTIL
                                                     81 BYTES

          1121 1921           CC1A00 JMP   WAIT     WAIT FOR INTERRUPT OR
                                                     RESET EXTERNAL
                                                     INTERRUPTS ENABLED
                                                     POWER DOWN
```

(SEND DATA/CHECK ECHO SUBROUTINE)

```
          1124 1924  ULOAD6   CD1E00 JSR   SEND C
          1127 1927           CD1E40 JSR   REC C    WAITING FOR ECHO
          112A 192A           B110   CMP   0010,A   CHECK FOR PROPER ECHO
          112C 192C           2703   BEQ   ULOAD3
          112E 192E           CC1E80 JMP   BADCOM   BAD ECHO, GO TO
                                                     `BAD COMMUNICATION'
          1131 1931  ULOAD3   81     RTS
                              -----
                              [50]
```

```
                (POWER DOWN MODE - WAITING FOR INTERRUPTS)
1200 1A00   WAIT    8F      WAIT          WAIT FOR INTERRUPT OR
                                            RESET EXTERNAL
                                          INTERRUPTS ENABLED
                                           POWER DOWN
                    [1]
```

TIMER INTERRUPT
(RTC ALARM - 1/MIN)
(INTERRUPT MASK BIT SET AUTOMATICALLY UPON INTERRUPT)

```
                (ALLOW ONLY EXTERNAL INTERRUPTS)
1300 1B00   MINUTE  1C09    BSET6 TCR6    (5) MASK TIMER
                                              INTERRUPTS
1302 1B02           9D      NOP           ( )
1303 1B03           9C      RSP           ( ) DON'T USE UP
                                              STACK
1304 1B04           9A      CLI           (2) ALLOW EXTERNAL
                                              INTERRUPTS
                                          ----
                                          (12) 1.8 mSec
```

```
            (TIMER INTERRUPT INDICATOR - FOR DEBUG ONLY)
1305 1B05   MINUT1  1400    BSET2 PA2     TURN ON GREEN LED -
                                            TIMER INT. INDIC.
```

```
                    (UPDATE HOURS, MINUTES AND DAY)
     1307 1B07          CD1F30 JSR   RTCRED  ACTUAL HOURS IN 0018
                                              (`HOURS')
                                             ACTUAL MINUTES IN
                                              0019 (`MINUTS')
                                             DAY OF WEEK IN 0010
                                              (`ATEMP')

     130A 1B0A          B610   LDA   ATEMP   CURRENT DAY OF WEEK
     130C 1B0C          B11A   CMP   DAYWEK  HAS DAY OF WEEK
                                              CHANGED?
     130E 1B0E          2704   BEQ   BELLOK
     1310 1B10          B71A   STA   DAYWEK  UPDATE DAY OF WEEK
                                              REFERENCE
     1312 1B12          3C16   INC   DAYCNT  UPDATE ACTUAL DAYS
                                              COUNT
     ------------------------------------------------------------

                    (ACTUAL VS TARGET TIME TESTS)
     1314 1B14  BELLOK  B617   LDA   @DAY
     1316 1B16          4C     INC   ACCA
     1317 1B17          B116   CMP   DAYCNT  IS TD+1 < AD ?
     1319 1B19          2406   BHS   MINUT2
                        (AD > TD + 1)
     131B 1B1B          CD13C0 JSR   ADVTGT  VERY LATE - ADVANCE
                                              TARGET

     131E 1B1E          CC1B14 JMP   BELLOK  RESTART
     1321 1B21  MINUT2  2620   BNE   MINUT3
                        (AD = TD + 1)
     1323 1B23          B618   LDA   HOURS
     1325 1B25          AB18   ADD   #24
     1327 1B27          B111   CMP   0011    IS HOURS + 24 >=
                                              @HOUR2 - 1
```

(ACTUAL VS TARGET TIME TESTS, continued)

```
1329 1B29          2506   BLO   MINUT4
132B 1B2B          CD1EC0 JSR   ADVTGT  VERY LATE - ADVANCE
                                        TARGET
132E 1B2E          CC1B14 JMP   BELLOK  RESTART
1331 1B31 MINUT4   CD1E90 JSR   UNLOCK  LATE ALL - UNLOCK IF
                                        LOCKED & RING BELL
1334 1B34 MINT11   CD1EA2 JSR   BELL    RING BELL FOUR TIMES
1337 1B37          CD1EA2 JSR   BELL
133A 1B3A          CD1EA2 JSR   BELL
133D 1B3D          CD1EA2 JSR   BELL
1340 1B40          CC1B95 JMP   MINT15  EXIT
1343 1B43 MINUT3   B616   LDA   DAYCNT
1345 1B45          B117   CMP   @DAY
1347 1B47          252F   BLO   MINUT5
                   (ACTUAL DAY = TARGET DAY)
1349 1B49          B618   LDA   HOURS
134B 1B4B          B111   CMP   0011    IS HOURS < @HOUR2 - 1?
134D 1B4D          2506   BLO   MINUT6
134F 1B4F          CD1EC0 JSR   ADVTGT  VERY LATE - ADVANCE
                                        TARGET
1352 1B52          CC1B14 JMP   BELLOK  RESTART
1355 1B55 MINUT6   B114   CMP   @HOUR
1357 1B57          2503   BLO   MINUT7
1359 1B59          CC1B31 JMP   MINUT4  LATE - UNLOCK & RING
                                        BELL
135C 1B5C MINUT7   4C     INC   ACCA
135D 1B5D          B114   CMP   @HOUR   DOES HOURS=@HOUR - 1?
135F 1B5F          2611   BNE   MINUT8
                   (WITHIN 1 HOUR)
1361 1B61 MINT14   B619   LDA   MINUTS
1363 1B63          C10126 CMP   0126    CHECK UNLOCK PERIOD
1366 1B66          2505   BLO   MINUT9
```

(ACTUAL VS. TARGET TIME TESTS, continued)

```
     1368 1B68           CD1E90 JSR   UNLOCK  UNLOCK IF NECESSARY
                                                  (AM >= UP)
     136B 1B6B           B619   LDA   MINUTS
     136D 1B6D  MINUT9   C10127 CMP   0127    CHECK ALARM PERIOD
     1370 1B70           2403   BHS   MINT10
     1372 1B72  MINUT8   CC1B95 JMP   MINT15  EARLY - EXIT
     1375 1B75  MINT10   CC1B34 JMP   MINT11  RING BELL & EXIT
                                                  (AM >= AP)
```

```
     1378 1B78  MINUT5   4C     INC   ACCA    DAYCNT + 1
     1379 1B79           B117   CMP   @DAY    DOES AD = TD - 1 ?
     137B 1B7B           2613   BNE   MINT12
                         (AD = TD -1)
     137D 1B7D           3D14   TST   @HOUR
     137F 1B7F           2609   BNE   MINT13
                         (@HOUR = 0)
     1381 1B81           B618   LDA   HOURS
     1383 1B83           A117   CMP   #23
     1385 1B85           2603   BNE   MINT13
                         (AH = 23)
     1387 1B87           CC1B61 JMP   MINT14  GO TO WITHIN 1 HOUR
                                                  TESTS
     138A 1B8A  MINT13   B618   LDA   HOURS
     138C 1B8C           B114   CMP   @HOUR
     138E 1B8E           2208   BHI   MINT16  <24 HOURS EARLY -
                                                  EXIT

     1390 1B90  MINT12   CD1F80 JSR   DASH    >24 HOURS EARLY -
                                                  DISPLAY DASH
     1393 1B93           2003   BRA   MINT16  EXIT WITHOUT
                                                  DISTURBING DASH
```

(ACTUAL VS TARGET TIME TESTS, continued)

```
1395 1B95   MINT15  CD1EEB JSR   CLKADV  UPDATE CLOCK TO CLEAR
                                          OBSOLETE DASH
1398 1B98   MINT16  C6010C LDA   010C    READ RTC REG C TO
                                          CLEAR ALARM FLAG

139B 1B9B           A601   LDA   #$01
139D 1B9D           B708   STA   TIDATA  LOAD TIMER WITH ONE
                                          COUNT
139F 1B9F           1F09   BCLR7 TCR7    CLEAR TIMER INTERRUPT
                                          REQUEST
13A1 1BA1           1D09   BCLR6 TCR6    ALLOW TIMER INTERRUPTS
          ------------------------------------------------
13A3 1BA3           1500   BCLR2 PA2     TURN OFF GREEN LED -
                                          TIMER INT. INDIC.
          ------------------------------------------------

13A5 1BA5           CC1A00 JMP   WAIT    BACK TO `WAIT'
                    -----
                    [    ]
-------------------------------------------------------------
```

EXTERNAL INTERRUPT

(DOSAGE TAKEN - ACTIVE MICROSWITCH ACTUATION)

(INTERRUPT MASK BIT SET AUTOMATICALLY UPON INTERRUPT)

(EXTERNAL INTERRUPT INDICATOR - FOR DEBUG ONLY)

```
1500 1D00   DOSAGE  1600   BSET3 PA3     (5) LIGHT RED LED -
                                          EXT. INT. INDIC.
          ------------------------------------------------
```

```
                (INTERCHANGE INTERRUPT SWITCH ACTIVATION)
     1502 1D02          B600   LDA   PORTA   (3)
     1504 1D04          A8C0   EOR   #$C0    (2) 1100 0000
     1506 1D06          B700   STA   PORTA   (4) PA7 & PA6 STATES
5                                                CHANGED
          ------------------------------------------------------

                        (READ/PACK/STORE DATA)
     1508 1D08          CD1F30 JSR   RTCRED  (6) GET CURRENT HOUR,
                                                 MINUTE,DAY DATA
     150B 1D0B          3C1C   INC   DOSTKN  (5) INCREMENT DOSES
10                                               TAKEN COUNTER
     150D 1D0D          CD1F50 JSR   PACK    (6) PACK/STORE DAY &
                                                 TIME DATA
          ------------------------------------------------------

                        (CHECK FOR UNIT EMPTY)
     1510 1D10          B61C   LDA   DOSTKN  ( )
15   1512 1D12          C1013B CMP   013B    ( ) TEST AGAINST
                                                 TOTAL # OF
                                                 DOSAGES, TD
     1515 1D15          2508   BLO   DOSAG1  ( )
     1517 1D17          CD1F80 JSR   DASH    DISPLAY DASH
20   151A 1D1A          1E00   BSET7 PA7     MICROSWITCHES
     DEACTIVATED - NO EXT.INT
     151C 1D1C          1C00   BSET6 PA6
     151E 1D1E          8E     STOP          WAIT FOR RESET -
                                                 POWER DOWN
          ------------------------------------------------------

25             (ADVANCE TARGET REGISTERS & UPDATE DISPLAY)
     151F 1D1F  DOSAG1  CD1EC0 JSR   ADVTGT  ( ) ADVANCE TARGETS
          ------------------------------------------------------
     1522 1D22          1700   BCLR3 PA3     ( ) RED LED OFF
          ------------------------------------------------------
```

```
      (EXIT TO MINUTE FOR BELL AND UNLOCK CHECK & THEN WAIT)
1524 1D24          CC1B00 JMP   MINUTE
                   ----
                   [  ]

-------------------------------------------------------------------
SUBROUTINES:
-------------------------------------------------------------------
                (SERIAL OUTPUT CHARACTER MUST BE IN A)
                (USES REG A, REG X, 0010, 0011, 0012)
              (ALTERS A, RESTORES X, CHARACTER IN 0010)
1600 1E00  SEND C  BF13   STX   XTEMP   (4) STORE X FOR LATER
                                            RESTORATION
1602 1E02          B710   STA   ATEMP   (4)
1604 1E04          B711   STA   CHAR    (4) STORE CHARACTER
                                            IN 0010 FOR ECHO
                                            CHECK & IN 0011
                                            FOR SENDING
1606 1E06          A609   LDA   #9      (2) OUTPUT 9 BITS
                                            (8 + START)
1608 1E08          B712   STA   COUNT   (4) BIT COUNTER IN
                                            0012
160A 1E0A          2008   BRA   SENDC3  (3) BRANCH TO OUTPUT
                                            A 0 (START BIT)
                                          ----
                                          (21)
-------------------------------------------------------------------

160C 1E0C  SENDC2  3611   ROR   CHAR    (5) MOVE NEXT BIT
                                            INTO CARRY
160E 1E0E  SENDC1  2404   BCC   SENDC3  (3) TEST FOR SET OR
                                            CLEAR BIT
1610 1E10          1A00   BSETS PA5           OUTPUT A 1
1612 1E12          2004   BRA   SENDC4        BRANCH TO DELAY
```

SUBSTITUTE SHEET

```
     1614 1E14   SENDC3   1B00    BCLR5 PA5      (5) OUTPUT A 0
     1616 1E16            2000    BRA   SENDC4   (3) EQUALIZE TIMING

     1618 1E18   SENDC4   CD1E30  JSR   DELAY    (6) TO TIMING DELAY
                                                    FOR 110 BAUD
     161B 1E1B            3A12    DEC   COUNT    (5) DECREMENT BIT
                                                    COUNTER
     161D 1E1D            26ED    BNE   SENDC2   (3) TEST IF ANOTHER
                                                    BIT TO SEND
                                                  ----
                                                  (60) CYCLES BETWEEN
                                                    BITS
     ------------------------------------------------------------

     161F 1E1F   STOPBT   9D      NOP            (2) 8 CYCLE DELAY
     1620 1E20            9D      NOP            (2)
     1621 1E21            9D      NOP            (2)
     1622 1E22            9D      NOP            (2)
     1623 1E23            1A00    BSET5 PA5      (5) SEND STOP BIT
     1625 1E25            CD1E30  JSR   DELAY    (6) DELAY FOR THE
                                                    STOP BIT
     ------------------------------------------------------------

     1628 1E28            BE13    LDX   0013     (3) RESTORE X
     162A 1E2A            81      RTS            (6) RETURN
                          [43]                       ASSUMES 8 CYCLES
                                                     TO REENTER SEND C
                                                     (129 CYCLES
                                                     BETWEEN
                                                     CHARACTERS)
     ------------------------------------------------------------
```

```
        30 CYCLE (4.58 mSec) DELAY FOR SEND/RECEIVE SUBROUTINES
              (ALTERS X UNLESS USED BY SEND C OR REC C)
1630 1E30   DELAY   AE03   LDX   #$03    (2) COUNTER SET TO 3
            ------------------------------------------------

1632 1E32   DELAY1  5A     DECX  X       (3) DECREMENT LOOP
                                             COUNTER
1633 1E33           26FD   BNE   DELAY1  (3) LOOP
            ------------------------------------------------

1635 1E35           9D     NOP           (2) EQUALIZATION
1636 1E36           9D     NOP           (2) EQUALIZATION
            ------------------------------------------------

1637 1E37           81     RTS           (6) RETURN TO SEND C
                                             OR REC C
                    [8]                  ----
                                         (30) 2+3*6+10 = 30
            ------------------------------------------------

                 (SERIAL INPUT CHARACTER GOES INTO A)
                       (ALTERS A, RESTORES X)
1640 1E40   REC C   BF13   STX   XTEMP   STORE REG X FOR LATER
                                             RESTORATION
1642 1E42           A608   LDA   #8
1644 1E44           B712   STA   COUNT   NUMBER OF DATA BITS
                                             TO READ
1646 1E46   REC C1  0000FD BRSET REC C1  TESTS FOR HI TO LO
                                             START BIT
                                             TRANSITION ON PA0
            ------------------------------------------------
```

```
1649 1E49   1/2DLY  AE04   LDX   #04     (2) DELAY 1/2 BIT
                                             TIME (30 CYCLES)
164B 1E4B   DLY1    5A     DECX  X        (3) DECREMENT COUNTER
164C 1E4C           26FD   BNE   DLY1     (3) LOOP
164E 1E4E           9D     NOP            (2) TIMING
                                             EQUALIZATION
164F 1E4F           9D     NOP            (2)   "        "
                                           ----
                                           (30)
```

(NOW IN MIDDLE OF START BIT)

```
1650 1E50   FALSE   0000F3 BRSET REC C1   (5) FALSE START BIT
                                             TEST
1653 1E53           9D     NOP            (2) TIMING
                                             EQUALIZATION
1654 1E54           9D     NOP            (2)   "        "
1655 1E55           9D     NOP            (2)   "        "
1656 1E56           9D     NOP            (2)   "        "
1657 1E57           9D     NOP            (2)   "        "
1658 1E58           2000   BRA   REC C2    (3)   "        "
                                           ----
                                           (18)
```

```
                                (MAIN RECEIVE ROUTINE)
     165A 1E5A   REC C2  CD1E30 JSR   DELAY   (6) ONE BIT TIMING
                                                DELAY
     165D 1E5D           9D     NOP           (2) 6 CYCLE
                                                EQUALIZATION
     165E 1E5E           9D     NOP           (2)
     165F 1E5F           9D     NOP           (2)
     1660 1E60           010000 BRCLR REC C3  (5) TEST INPUT (PA0)
                                                AND SET C-BIT
     1663 1E63   REC C3  3611   ROR   CHAR    (5) ASSEMBLE
                                                CHARACTER
     1665 1E65           3A12   DEC   COUNT   (5) DECREMENT BIT
                                                COUNTER
     1667 1E67           26F1   BNE   REC C2  (3) TEST FOR MORE
                                                BITS TO READ
                                               -----
                                               (60) CYCLES BETWEEN
                                                BITS
     ------------------------------------------------------------

     1669 1E69           CD1E30 JSR   DELAY   WAIT OUT THE 9TH
                                                (STOP) BIT
     ------------------------------------------------------------

     166C 1E6C           B611   LDA   CHAR    PUT ASSEMBLED BYTE
                                                INTO A

     166E 1E6E           BE13   LDX   0013    RESTORE X
     1670 1E70           81     RTS           RETURN
                         ----
                         [49]
     ------------------------------------------------------------
```

```
                (BAD COMMUNICATION - SENDS ASCII 30 AND WAITS)
    1680 1E80   BADCOM  9C      RSP           RESET STACK POINTER
    1681 1E81           A61E    LDA   #$1E     ASCII 30
    1683 1E83           CD1E00  JSR   SEND C  SEND ASCII 30 (BAD
                                                 COMMUNICATION)
    1686 1E86           CC1A00  JMP   WAIT     WAIT FOR RESTART
                        ----                   (RESET WILL RESET SP
                                                 TO 7F)
                        [9]
    ------------------------------------------------------------

                (UNLOCK SOLENOID ON FOR 50 mSec)
                    (ALTERS A, ALTERS X)

                (TEST UNLOCK SWITCH)
    1690 1E90   UNLOCK  020001 BRSET1UNLCK1  IS SPROCKET LOCKED ?
                                                 (PA1 = 1)
    1693 1E93           81      RTS           EXIT - ALREADY
                                                 UNLOCKED
               ---------------------------------------------------
    1694 1E94   UNLCK1  1800    BSET4 PA4     TURN ON UNLOCK
                                                 SOLENOID
               ---------------------------------------------------
    1696 1E96           A60B    LDA   #11      11*4.58=50 mSec
                                                 ON DELAY
    1698 1E98   UNLCK2  CD1E30  JSR   DELAY
    169B 1E9B           4A      DEC   A
    169C 1E9C           26FA    BNE   UNLCK2   LOOP
               ---------------------------------------------------
    169E 1E9E           1900    BCLR4 PA4     TURN OFF UNLOCK
                                                 SOLENOID
               ---------------------------------------------------
    16A0 1EA0           81      RTS
                        ----
                        [17]
    ------------------------------------------------------------
```

```
                (PIEZO ALARM ON FOR 100 mSec / OFF FOR 500 mSec)
                          (ALTERS X, ALTERS A)

     16A2 1EA2   BELL     1E01   BSET7 PB7      BELL ON
                 ------------------------------------------------------

     16A4 1EA4            A610   LDA   #16      ON DELAY OF 6.4 * 16
                                                   = 100 mSec
     16A6 1EA6   BELL01   CD1E30 JSR   DELAY
     16A9 1EA9            4A     DEC   A
     16AA 1EAA            26FA   BNE   BELL01
                 ------------------------------------------------------

     16AC 1EAC            1F01   BCLR7 PB7      BELL OFF
                 ------------------------------------------------------

     16AE 1EAE            A650   LDA   #80      500 mSec OFF DELAY
     16B0 1EB0   BELL02   CD1E30 JSR   DELAY
     16B3 1EB3            4A     DEC   A
     16B4 1EB4            26FA   BNE   BELL02
                 ------------------------------------------------------

     16B6 1EB6            81     RTS
                          ----
                          [21]
     ------------------------------------------------------------------
```

```
                    (INCREMENT `NEXTHR', `@DAY' IF NECESSARY)
                      (UPDATE `@HOUR' & `@HOUR2' & DISPLAY)
     16C0 1EC0   ADVTGT  3C15   INC   NEXTHR  INCREMENT NEXT HOUR
                                                POINTER
     ------------------------------------------------------------
     16C2 1EC2           B615   LDA   NEXTHR
     16C4 1EC4           C1011A CMP   011A    COMPARE AGAINST SN
     16C7 1EC7           2504   BLO   ADVTG1
     16C9 1EC9           3F15   CLR   NEXTHR  WRAP NEXT HOUR
                                                POINTER TO 0
     16CB 1ECB           3C17   INC   @DAY    INCREMENT TARGET DAY
                                                COUNTER

     16CD 1ECD   ADVTG1  BE15   LDX   NEXTHR
     16CF 1ECF           D6011B LDA   011B,X
     16D2 1ED2           B714   STA   @HOUR   UPDATE TARGET HOUR
                                                REGISTER
     ------------------------------------------------------------

                      (DETERMINE UPCOMING TARGET HOUR)
     16D4 1ED4           5C     INC   ACCX
     16D5 1ED5           C3011A CPX   011A    COMPARE AGAINST SN
     16D8 1ED8           2507   BLO   ADVTG2
     16DA 1EDA           C6011B LDA   011B    SC(0)
     16DD 1EDD           AB18   ADD   #24     +24 IF NEXT DAY
     16DF 1EDF           2003   BRA   ADVTG3
     16E1 1EE1   ADVTG2  D6011B LDA   011B,X
     16E4 1EE4   ADVTG3  B71B   STA   @HOUR2  UPDATE UPCOMING
                                                TARGET HOUR
     16E6 1EE6           B61B   LDA   @HOUR2
     16E8 1EE8           4A     DEC   ACCA
     16E9 1EE9           B711   STA   0011    @HOUR2 - 1 INTO
                                                `CHAR'
     ------------------------------------------------------------
```

```
                    (LCD UPDATE TO NEXT DOSING HOUR)
                              (AM/PM CHECK)
     16EB 1EEB   CLKADV  B614   LDA   @HOUR
     16ED 1EED           A10B   CMP   #11     TEST FOR AM OR PM
     16EF 1EEF           2204   BHI   PM
     16F1 1EF1           A630   LDA   #$30    AM
     16F3 1EF3           2002   BRA   CLK1
     16F5 1EF5   PM      A632   LDA   #$32    PM
     16F7 1EF7   CLK1    CD1F25 JSR   LCDOUT  DIGIT 1 UPDATED
                         (CONVERT FROM 24 TO 12 HOUR)
     16FA 1EFA           B614   LDA   @HOUR
     16FC 1EFC           4D     TST   ACCA
     16FD 1EFD           2604   BNE   CLK2
     16FF 1EFF           AB0C   ADD   #12     0 CONVERTED TO 12
     1701 1F01           2006   BRA   CLK3
     1703 1F03   CLK2    A10C   CMP   #12
     1705 1F05           2302   BLS   CLK3
     1707 1F07           A00C   SUB   #12   13-23 CONVERTED TO 1-11
                    (HOUR SEPARATED INTO ONES AND TENS DIGITS)
     1709 1F09   CLK3    A10A   CMP   #10
     170B 1F0B           250D   BLO   CLK4
     170D 1F0D           A00A   SUB   #10
     170F 1F0F           AB10   ADD   #16     DS1=1 DS2=0
     1711 1F11           CD1F25 JSR   LCDOUT  DIGIT 3 LOADED WITH
                                                 0,1, OR 2
     1714 1F14           A601   LDA   #01
     1716 1F16           CD1F25 JSR   LCDOUT  DIGIT 4 LOADED WITH 1
     1719 1F19           81     RTS           EXIT
     171A 1F1A   CLK4    AB10   ADD   #16
     171C 1F1C           CD1F25 JSR   LCDOUT  DIGIT 3 LOADED WITH
                                                 0-9
     171F 1F1F           A60F   LDA   #$0F
     1721 1F21           CD1F25 JSR   LCDOUT  DIGIT 4 BLANKED
     1724 1F24           81     RTS           EXIT
                         [ ]
```

```
                                (LOAD DISPLAY DIGIT)
     1725 1F25   LCDOUT  B701   STA   PORT B  DIGIT & DS1,DS2 DATA
                                                 TO 7211
     1727 1F27           1D01   BCLR6 PB6      CHIP SELECTS GO LOW
                                                 (LATCH INPUT)
     1729 1F29           1C01   BSET6 PB6      CHIP SELECTS GO HI
                                                 (LATCH OUTPUT)
     172B 1F2B           81     RTS
                         ----
                         [ ]
     ------------------------------------------------------------

                          (READ RTC HOURS & MINUTES)
     1730 1F30   RTCRED  C6010C LDA   010C     (4) READING RTC REG C
                                                 CLEARS PF BIT
     1733 1F33   RTCRD1  C6010C LDA   010C     (4) (4) (4) LOAD REG
                                                 C FOR TESTING
     1736 1F36           A440   AND   #$40     (2) (2) (2) LOOKING
                                                 FOR BIT 6 (PF)
                                                 HIGH
     1738 1F38           27F9   BEQ   RTCRD1   (3) (3) (3) LOOP IF
                                                 PF NOT SET
     173A 1F3A           C60104 LDA   0104     (4) (4) LOAD CURRENT
                                                 HOURS
     173D 1F3D           B718   STA   HOURS    (4) (4) STORE (000H
                                                 HHHH) IN `HOURS'
     173F 1E3F           C60102 LDA   0102     (4) (4) LOAD CURRENT
                                                 MINUTES
     1742 1F42           B719   STA   MINUTS   (4) STORE (00MM MMMM)
                                                 IN `MINUTS'
```

```
     1744 1F44          C60106 LDA   0106    (4) LOAD DAY OF WEEK
     1747 1F47          B710   STA   ATEMP   STORE IN `ATEMP'
     1749 1F49          81     RTS           (6)
                        ----                 ------------
 5                      [ ]                     (  )+(  ) = mSec
                                                MINIMUM VALID
                                                ACCESS TIME
                                                REQUIRED
                                              . 7.5 mSec (1/2 PI)
10                                              IS AVAILABLE
```

```
                    (PACK DATA INTO TWO BYTES & STORE)
     1750 1F50  PACK   3419   LSR   MINUTS  (5) DIVIDES MINUTES
                                                BY 2 (000M MMMM)
     1752 1F52         BE1C   LDX   DOSCNT  (3) LOAD X WITH
15                                              MEMORY POINTER
     1754 1F54         58     LSL   X        (3) MULTIPLY MEMORY
                                                POINTER X2

     1755 1F55         B616   LDA   DAYCNT  (3) (00DD DDDD)
     1757 1F57         48     LSL   A        (3)
20   1758 1F58         48     LSL   A        (3) (DDDD DD00)
     1759 1F59         A4E0   AND   #$E0     (2) (DDD0 0000)
                                                DAYS HI
     175B 1F5B         BB19   ADD   MINUTS   (3) (DDDM MMMM)
                                                DAYS HI + MINUTES
25   175D 1F5D         A11A   CMP   #26      (2) CHECK FOR BREAK
                                                CODE
     175F 1F5F         2602   BNE   PACK1    (3) OK
     1761 1F61         A61F   LDA   #31      (2) CHANGE 26 TO 31
     1763 1F63  PACK1  E71C   STA   001C,X   (6) PACKED DATA STORED
30                                              IN 146805 RAM
```

```
     1765 1F65          B616   LDA   DAYCNT  (3) (OODD DDDD)
     1767 1F67          48     LSL   A       (3)
     1768 1F68          48     LSL   A       (3)
     1769 1F69          48     LSL   A       (3)
 5   176A 1F6A          48     LSL   A       (3)
     176B 1F6B          48     LSL   A       (3) (DDDO 0000)
                                                  DAYS LO
     176C 1F6C          BB18   ADD   HOURS   (3) (DDDH HHHH)
                                                  DAYS LO + HOURS
10   176E 1F6E          A11A   CMP   #26     (2) CHECK FOR BREAK
                                                  CODE
     1770 1F70          2602   BNE   PACK2   (3) OK
     1772 1F72          A61F   LDA   #31     (2) CHANGE 26 TO 31
     1774 1F74  PACK2   E71B   STA   001B,X  (6) PACKED DATA STORED
15                                                IN 146805 RAM
                ------------------------------------------------
     1776 1F76          81     RTS           (6)
                        ----                 -----
                        [  ]                 (   ) =      mSec
20   ------------------------------------------------------------

                    (PUT DASH IN HOUR DISPLAY)
     1780 1F80  DASH    A60F   LDA   #$0F
     1782 1F82          CD1F25 JSR   LCDOUT  DIGIT 4 BLANKED

     1785 1F85          A61A   LDA   #$1A
25   1787 1F87          CD1F25 JSR   LCDOUT  DIGIT 3 LOADED WITH
                                                  A DASH
     178A 1F8A          A630   LDA   #$30
     178C 1F8C          CD1F25 JSR   LCDOUT  DIGIT 1 LOADED WITH
                                                  AN A
30   178F 1F8F          81     RTS
                        ----
                        [  ]
     ------------------------------------------------------------
```

IDENTIFYING ASCII

17E0	1FE0	4D	M
17E1	1FE1	4D	M
17E2	1FE2	53	S
17E3	1FE3	40	@
17E4	1FE4	30	0
17E5	1FE5	38	8
17E6	1FE6	2F	/
17E7	1FE7	32	2
17E8	1FE8	32	2
17E9	1FE9	2F	/
17EA	1FEA	38	8
17EB	1FEB	34	4

INTERRUPT VECTORS:

17F6	1FF6	1B00	TIMER INTERRUPT FROM WAIT - 1B00 (`MINUTE')
17F8	1FF8	1B00	TIMER INTERRUPT - 1B00 (`MINUTE')
17FA	1FFA	1D00	EXTERNAL INTERRUPT - 1D00 (`DOSAGE')
17FC	1FFC	1B00	SWI - 1B00 (`MINUTE')
17FE	1FFE	1800	RESET - 1800 (`RESET')

[10]

[ ]

CONTROLLED DISPENSING DEVICE
"LOAD-M" PROGRAM LISTING

APPENDIX II

```
10   REM          LOAD-M
20   REM          10/13/84
30   REM          REV 04
40   CLEAR
50   MAXFILES=2
90   ON ERROR GOTO 430
95   REM ----------LOGO----------
100  CLS:LINE (10,2)-(228,60),1,B:LINE (12,4)-(226,58),1,B
110  PRINT @47,"MEDICAL MICROSYSTEMS, INC."
120  PRINT @133,"Copyright 1984"
130  PRINT @248,"Monitor Loading Routine"
135  PRINT @275,"A4"
140  FOR I=1 TO 1000:NEXT I
145  REM ----------ENTER DATA---------
150  CLS:LINE (184,30)-(221,41),1,B
160  PRINT @163,"";:LINE INPUT "ENTER STUDY ID.# (6 Digits)
       ";SI$
161  LE=LEN(SI$):IF LE>6 THEN SI$=LEFT$(SI$,6)
162  IF LE<6 THEN 164 ELSE 170
164  FOR I=1 TO 6-LE:SI$=" "+SI$:NEXT I
170  CLS:LINE (190,30)-(227,41),1,B
180  PRINT @162,"";:LINE INPUT "ENTER PATIENT ID.#
       (6 DIGITS)        ";PI$
181  LF=LEN(PI$):IF LF>6 THEN PI$=LEFT$(PI$,6)
182  IF LF<6 THEN 184 ELSE 185
184  FOR I=1 TO 6-LF:PI$=" "+PI$:NEXT I
185  DIM SC(3),TI$(3),D$(49),IN(3)
190  SN=0:CLS:LINE (8,11)-(189,44),1,B
200  LINE (200,19)-(213,36),1,B:LINE(218,19)-(231,36),1,B
210  PRINT @1,"DAILY SCHEDULE SELECTION (1-4 Entries)"
```

```
220  PRINT @83,"1   AM    11   1   PM    11"
230  PRINT @123,"212345678901   212345678901"
240  PRINT @154,"X":PRINT @157,"C"
250  PRINT @241,"Move cursor over hour and press 'ENTER'";
260  PRINT @286,"Restart - X     Complete - C";
270  PRINT @122,"";
280  A$=INPUT$(1)
290  IF ASC(A$)=28 THEN PRINT @(120+POS(0)+1),"";
300  IF ASC(A$)=29 THEN PRINT @(120+POS(0)-1),"";
310  IF ASC(A$)<>13 THEN 280
320  IF CSRLIN<>3 THEN 280
330  IF POS(0)=34 THEN 190
340  IF POS(0)=37 THEN 440
350  IF POS(0)>29 OR POS(0)<3 THEN 280
360  IF POS(0)>14 AND POS(0)<18 THEN 280
370  IF POS(0)>14 THEN 390
380  SC(SN)=POS(0)-3:LA=SC(SN):IF LA=0 THEN LA=12
385  TI$(SN)=STR$(LA)+" AM":GOTO 393
390  SC(SN)=POS(0)-6:LA=SC(SN)-12:IF LA=0 THEN LA=12
392  TI$(SN)=STR$(LA)+" PM"
393  IF SN=0 THEN 395
394  IF SC(SN)<SC(SN-1) THEN 280
395  IF LA<10 THEN TI$(SN)=" "+TI$(SN)
400  IF LA>9 THEN LA=LA-10
405  L$=MID$(STR$(LA),2)
410  PRINT @(160+POS(0)),L$;:PRINT @(120+POS(0)),"";
420  SN=SN+1:IF SN=4 THEN 460
425  GOTO 280
430  IF ERR=9 THEN RESUME 190
431  CLS:PRINT "ERROR";ERR:END
432  IF ERR=2 THEN RESUME 1200
434  PRINT "ERROR";:FOR I=1 TO 500:NEXT I:RESUME
440  IF SN=0 THEN 190
450  IF SN=1 THEN D1=0:GOTO 620
460  CLS:PRINT @8,"SELECT FIRST DOSAGE TIME";
```

```
470  FOR I=0 TO SN-1:PRINT @128+I*8,TI$(I);:NEXT I
480  PRINT @240,"Move box over first dosage & press ENTER";
490  LINE (3,20)-(39,36),1,B:PRINT @80,"";
500  A$=INPUT$(1):L1=POS(0)*6+3:L2=(POS(0)+6)*6+3
510  IF ASC(A$)<>28 THEN 550
520  IF (POS(0)-8)/8=SN-1 THEN 500
530  LINE (L1,20)-(L2,36),0,B:LINE(L1+48,20)-(L2+48,36),1,B
540  PRINT @88+POS(0),"";:GOTO 500
550  IF ASC(A$)<>29 THEN 590
560  IF POS(0)<9 THEN 500
570  LINE(L1,20)-(L2,36),0,B:LINE(L1-48,20)-(L2-48,36),1,B
580  PRINT @72+POS(0),"";:GOTO 500
590  IF ASC(A$)<>13 THEN 500
600  IF POS(0)=0 THEN 500
610  D1=(POS(0)-8)/8
620  CLS:PRINT @162,"";:LINE INPUT "ENTER STARTING DAY OFFSET
       ";SD$
630  SD=VAL(SD$)
640  CLS:PRINT @162,"";:LINE INPUT "ENTER # OF DOSES LOADED
       (1-40) ";TD$
650  TD=VAL(TD$)
700  CLS:LINE(172,30)-(209,41),1,B
710  PRINT @166,"";:LINE INPUT "ENTER MONITOR SERIAL # ";SN$
715  LG=LEN(SN$):IF LG>6 THEN SN$=LEFT$(SN$,6)
720  IF LG<6 THEN 730 ELSE 800
730  FOR I=1 TO 6-LG:SN$=" "+SN$:NEXT I
800  I=1
801  IF I=7 THEN 805
802  IF MID$(SN$,I,1)=" " THEN I=I+1:GOTO801
804  IF MID$(SN$,I,1)="L" THEN 810
805  UP$="  ALWAYS":UP=0:GOTO 1000
810  CLS:PRINT @10,"SELECT UNLOCK PERIOD";
820  PRINT @96,"  2 Min.";CHR$(155);
830  PRINT @136," 30 Min.";
840  PRINT @176," 59 Min.";
```

```
850  PRINT @217,"Always";
860  PRINT @280,"Move arrow to selection and press
        ENTER";:PRINT @105,"";
870  A$=INPUT$(1)
880  IF ASC(A$)<>31 THEN 920
890  IF CSRLIN=5 THEN 870
900  GOSUB 910:PRINT @(CSRLIN+1)*40+24,CHR$(155);:GOTO 870
910  LINE (144,16)-(149,48),0,BF:RETURN
920  IF ASC(A$)<>30 THEN 950
930  IF CSRLIN=2 THEN 870
940  GOSUB 910:PRINT @(CSRLIN-1)*40+24,CHR$(155);:GOTO 870
950  IF ASC(A$)<>13 THEN 870
960  UP=CSRLIN-1
970  ON UP GOTO 972,974,976,978
972  UP$="  2 Min.":UP=58:GOTO 1000
974  UP$=" 30 Min.":UP=30:GOTO 1000
976  UP$=" 59 Min.":UP=1:GOTO 1000
978  UP$="  ALWAYS":UP=61
1000 CLS:PRINT @11,"SELECT ALARM START";
1010 PRINT @97," 2 Min.";CHR$(155);
1020 PRINT @137,"15 Min.";
1030 PRINT @177,"30 Min.";
1040 PRINT @219,"NONE";
1050 PRINT @280,"Move arrow to selection and press
        ENTER";:PRINT @105,"";
1060 A$=INPUT$(1)
1070 IF ASC(A$)<>31 THEN 1100
1080 IF CSRLIN=5 THEN 1060
1090 GOSUB 910:PRINT @(CSRLIN+1)*40+24,CHR$(155);:GOTO 1060
1100 IF ASC(A$)<>30 THEN 1130
1110 IF CSRLIN=2 THEN 1060
1120 GOSUB 910:PRINT @(CSRLIN-1)*40+24,CHR$(155);:GOTO 1060
1130 IF ASC(A$)<>13 THEN 1060
1140 AP=CSRLIN-1
1150 ON AP GOTO 1160,1170,1180,1190
```

```
1160  AP$=" 2 Min.":AP=58:GOTO 1200
1170  AP$="15 Min.":AP=45:GOTO 1200
1180  AP$="30 Min.":AP=30:GOTO 1200
1190  AP$="   NONE":AP=61
1200  CLS:PRINT @48,"DATE IS: ";DATE$;
1210  PRINT @128,"TIME IS: ";TIME$;
1220  PRINT @205,"If correct press 'C'";
1230  PRINT @245,"If incorrect press 'I'";:PRINT @230,"";
1240  A$=INPUT$(1)
1250  IF ASC(A$)=67 THEN 1255 ELSE 1260
1255  DA$=DATE$:TM$=TIME$:GOTO 1400
1260  IF ASC(A$)<>73 THEN 1240
1270  LINE(0,32)-(239,63),0,BF
1280  PRINT @201,"Enter correct date using format shown";:PRINT
        @70,"";
1290  LINE INPUT DA$
1300  LINE(0,32)-(239,63),0,BF
1310  PRINT @201,"Enter correct time using format shown";:PRINT
        @150,"";
1320  LINE INPUT TM$
1330  DATE$=DA$:TIME$=TM$:GOTO 1200
1400  FOR I=1 TO 6:D$(I-1)=MID$(SI$,I,1):NEXT I
1410  FOR I=1 TO 6:D$(I+5)=MID$(PI$,I,1):NEXT I
1420  D$(12)=CHR$(SN):FOR I=1 TO 4:D$(I+12)=CHR$(SC(I-1)):NEXT
        I
1430  D$(17)=CHR$(D1)
1440  FOR I=1 TO 6:D$(I+17)=MID$(SN$,I,1):NEXT I
1450  D$(24)=CHR$(UP)
1460  D$(25)=CHR$(AP)
1470  FOR I=1 TO 8:D$(I+25)=MID$(DA$,I,1):NEXT I
1480  FOR I=1 TO 8:D$(I+33)=MID$(TM$,I,1):NEXT I
1490  D$(42)=CHR$(VAL(MID$(TM$,4,2)))
1492  IF ASC(D$(42))=26 THEN D$(42)=CHR$(27)
1495  D$(43)=CHR$(VAL(LEFT$(TM$,2)))
1496  D$(44)=CHR$(SD)
```

```
1497  D$(45)=CHR$(TD)
1498  IF ASC(D$(45))=26 THEN D$(45)=CHR$(27)
1508  FOR I=1 TO 4:D$(45+I)=CHR$(0):NEXT I
1509  REM ---------LOAD FIELD UNIT-------
1510  OPEN "COM:28N1D" FOR INPUT AS 1
1520  OPEN "COM:28N1D" FOR OUTPUT AS 2
1530  CLS:PRINT @41,"Verify that Monitor has fresh battery";
1540  PRINT @123,"Connect Interface Unit to Monitor";
1550  PRINT @169,"Turn On Interface Unit";
1560  PRINT @247,"Press Monitor Reset Switch";
1600  B$=INPUT$(1,1)
1610  IF B$<>"R" THEN 1620 ELSE 1650
1620  CLS:PRINT @91,"BAD COMMUNICATION";
1630  PRINT @175,"RESTARTING";
1640  FOR I=1 TO 500: NEXT I:GOTO 1530
1650  CLS:PRINT @0,"Communications Established";
1700  PRINT #2,"L";:B$=INPUT$(1,1):IF B$<>"L" THEN 1620
1710  PRINT @80,"Monitor Verifies Load Mode";
1800  PRINT #2,"C";:B$=INPUT$(1,1):IF B$<>"R" THEN 1620
1810  PRINT @160,"Loading Data";
1820  FOR I=0 TO 49:T$=D$(I):PRINT @176,I+1;:PRINT
         #2,T$;:E$=INPUT$(1,1)
1830  IF E$<>T$ THEN 2445
1835  NEXT I
1840  PRINT @240,"Data Transmission Complete";
1850  FOR I=1 TO 500:NEXT I
1860  CLS:PRINT @7,"Press key 'B' to test alarm";
1870  PRINT @89,"Press key 'U' to unlocK";
1900  PRINT @161,"Press Key 'C' When Tests Are Complete";
1920  PRINT @260,"";:A$=INPUT$(1):IF A$="Y" THEN 1990
1922  IF A$="B" THEN PRINT#2,"B";:GOTO 1920
1924  IF A$="U" THEN PRINT#2,"U";:GOTO 1920
1930  IF A$<>"C" THEN 1920
1990  PRINT #2,"C";
2000  B$=INPUT$(1,1):IF B$<>"F" THEN 1620
```

```
2005 REM ----------PRINT RECORD---------
2010 CLS:PRINT @46,"Monitor Loading Is Complete";
2020 PRINT @121,"Turn off and disconnect Interface Unit";
2030 PRINT @203,"Printer On?, Align Top, Press 'P'";
2040 PRINT @237,"";:A$=INPUT$(1)
2050 IF A$<>"P" THEN 2040
2060 PRINT @292,"Printing Record";
2100 LPRINT:LPRINT
2105 LPRINT TAB(27);"MONITOR LOAD RECORD"
2107 LPRINT:LPRINT
2110 LPRINT "Study I.D.#";TAB(65);SI$
2120 LPRINT:LPRINT
2130 LPRINT "Patient I.D.#";TAB(65);PI$
2140 LPRINT:LPRINT
2150 LPRINT STRING$(71,"-")
2160 LPRINT:LPRINT
2170 LPRINT "Delivery Schedule:";TAB(65);TI$(0)
2180 IF SN>1 THEN LPRINT:LPRINT TAB(65);TI$(1) ELSE 2210
2190 IF SN>2 THEN LPRINT:LPRINT TAB(65);TI$(2) ELSE 2210
2200 IF SN>3 THEN LPRINT:LPRINT TAB(65);TI$(3)
2210 LPRINT:LPRINT
2220 LPRINT "     First Dosage:";TAB(65);TI$(D1)
2230 LPRINT:LPRINT
2234 LPRINT "     Start Offset:";TAB(69);SD
2236 LPRINT:LPRINT
2237 LPRINT "     Doses Loaded:";TAB(68);TD
2238 LPRINT:LPRINT
2240 LPRINT STRING$(71,"-")
2250 LPRINT:LPRINT
2260 LPRINT "Monitor Serial #";TAB(65);SN$
2270 LPRINT:LPRINT
2280 LPRINT "  Unlock Period:";TAB(63);UP$
2290 LPRINT:LPRINT
2300 LPRINT "    Alarm Start:";TAB(64);AP$
2310 LPRINT:LPRINT
```

```
2320  LPRINT "Date Monitor Loaded:";TAB(63);DA$
2330  LPRINT:LPRINT
2340  LPRINT "Time Monitor Loaded:";TAB(63);TM$
2350  LPRINT CHR$(12):LPRINT CHR$(12)
2360  REM ------------EXIT-------------
2400  CLS:PRINT @166,"Load Another Unit? (Y or N)";
2410  PRINT @195,"";:A$=INPUT$(1)
2420  IF A$="Y" THEN CLEAR:GOTO 150
2430  IF A$<>"N" THEN 2410
2440  CLEAR:MENU
```

CONTROLLED DISPENSING DEVICE
"READ-M" PROGRAM LISTING

APPENDIX III

```
10  REM       READ-M
20  REM       10/13/84
30  REM       REV 05
100 CLS:LINE (10,2)-(228,60),1,B:LINE (12,4)-(226,58),1,B
110 PRINT @47,"MEDICAL MICROSYSTEMS, INC."
120 PRINT @133,"Copyright 1984"
130 PRINT @247,"Monitor Debriefing Routine"
135 PRINT @275, "A4"
140 FOR I=1 TO 1000:NEXT I
150 CLOSE:CLEAR
200 MAXFILES=2
205 DIM D$(134),SC(3),SC$(3),IN(3)
210 OPEN "COM:28N1D" FOR INPUT AS 1
220 OPEN "COM:28N1D" FOR OUTPUT AS 2
230 REM ---------------UNLOAD----------------------
300 CLS:PRINT @83,"Connect Interface Unit to Monitor";
310 PRINT @169,"Turn ON Interface Unit";
320 PRINT @247,"Press Monitor Reset Switch";
400 B$=INPUT$(1,1)
410 IF B$<>"R" THEN 420 ELSE 450
420 CLS:PRINT @91,"BAD COMMUNICATION";
430 PRINT @175,"RESTARTING";
440 FOR I=1 TO 500:NEXT I:GOTO 150
450 CLS:PRINT @0,"Communications Established";
460 PRINT #2,"U";:B$=INPUT$(1,1):IF B$<>"U" THEN 420
470 PRINT @80,"Monitor Verifies Unload Mode";
480 PRINT #2,"C";:PRINT @160,"Unloading Data";
485 ON ERROR GOTO 2000
490 FOR I=1 TO 131:R$=INPUT$(1,1)
495 D$(I-1)=R$
```

SUBSTITUTE SHEET

```
 496  IF I=25 OR I=26 OR I=43 OR I=46 THEN 510
 500  IF ASC(R$)=30 THEN 420
 510  PRINT @176,I;:PRINT #2,R$;:NEXT I
 530  PRINT @240,"Data Transmission Complete"
 540  FOR I=1 TO 500:NEXT I
 600  CLS:PRINT @45,"Monitor Unloading is Complete";
 610  PRINT @121,"Turn OFF and disconnect Interface Unit";
 620  PRINT @203,"Printer ON?, Align Top, Press 'P'";
 630  PRINT @237,"";:A$=INPUT$(1)
 639  IF A$<>"P" THEN 630
 640  PRINT @295,"Computing";
 641  REM ------------ASSEMBLE IDENTIFYING DATA----------------
 642  SI$=D$(0)+D$(1)+D$(2)+D$(3)+D$(4)+D$(5)
 644  PI$=D$(6)+D$(7)+D$(8)+D$(9)+D$(10)+D$(11)
 646  SN=ASC(D$(12))
 648  SC(0)=ASC(D$(13)):SC(1)=ASC(D$(14)):SC(2)=ASC(D$(15)):
        SC(3)=ASC(D$(16))
 650  D1=ASC(D$(17))
 651  SD=ASC(D$(44)):DT=ASC(D$(45))
 652  SN$=D$(18)+D$(19)+D$(20)+D$(21)+D$(22)+D$(23)
 654  UP=ASC(D$(24)):AP=ASC(D$(25))
 656  DA$=D$(26)+D$(27)+D$(28)+D$(29)+D$(30)+D$(31)
        +D$(32)+D$(33)
 658  TM$=D$(34)+D$(35)+D$(36)+D$(37)+D$(38)+D$(39)
        +D$(40)+D$(41)
 660  CT=ASC(D$(50)):IF CT>40 THEN CT=40
 661  ON SN GOTO 662,663,664,665
 662  IN(0)=24:GOTO 670
 663  IN(0)=SC(1)-SC(0):IN(1)=SC(0)+24-SC(1):GOTO 670
 664  IN(0)=SC(1)-SC(0):IN(1)=SC(2)-SC(1):IN(2)=SC(0)
        +24-SC(2):GOTO 670
 665  IN(0)=SC(1)-SC(0):IN(1)=SC(2)-SC(1):IN(2)=
        SC(3)-SC(2):IN(3)=SC(0)+24-SC(3)
 670  IF AP=58 THEN AP$="T-2 Minutes"
 672  IF AP=45 THEN AP$="T-15 Minutes"
```

```
674  IF AP=30 THEN AP$="T-30 Minutes"
676  IF AP=61 THEN AP$="No Alarm"
680  IF UP=58 THEN UP$="T-2 Minutes"
682  IF UP=30 THEN UP$="T-30 Minutes"
684  IF UP=1 THEN UP$="T-59 Minutes"
686  IF UP=61 THEN UP$="Always Unlocked"
690  FOR I=1 TO 4
692  IF SC(I-1)<10 THEN SC$(I-1)="0"+RIGHT$
        (STR$(SC(I-1)),1)+"00":GOTO 696
694  SC$(I-1)=RIGHT$(STR$(SC(I-1)),2)+"00"
696  NEXT I
698  D1$=SC$(D1)
699  REM ----------LCD REPORT----------
700  CLS:PRINT @2,"STUDY ID#:";SI$;
720  PRINT @21,"LOAD:";DA$;
735  PRINT " ";LEFT$(TM$,5);
740  PRINT @40,"PATIENT ID#:";PI$;
760  PRINT @59,"UNLOAD:";DATE$;" ";LEFT$(TIME$,5);
770  PRINT @91,"SCH: ";
780  FOR I=1 TO SN:PRINT " ";SC$(I-1);:NEXT I
920  LINE (0,24)-(239,63),1,B
930  LINE (0,43)-(239,43)
940  PRINT @200,"";
1000 J=51:K=D1:TT=((SD+1)*24+SC(D1))*60
1010 FOR I=1 TO CT
1030 GOSUB 1720
1040 IF TB<>6 THEN 1200
1050 PRINT @200+POS(0),"M";
1060 K=K+1:GOSUB 1220:TT=T1:GOSUB 1745:GOTO 1040
1200 PRINT @200+POS(0)+(TB-3)*40,"*";
1210 J=J+2:K=K+1:GOSUB 1220:TT=T1:GOTO 1230
1220 IF K=SN THEN K=0:Z=POS(0):LINE(Z*6-1,24)-(Z*6-1,63):
        PRINT @200+Z,"";
1225 RETURN
1230 NEXT I
```

```
1240  REM ----------------HARD COPY REPORT-------------------
1300  LPRINT:LPRINT
1310  LPRINT TAB(19);"COMPLIANCE MONITOR DEBRIEFING REPORT"
1320  LPRINT:LPRINT "Study I.D.#";TAB(65);SI$
1330  LPRINT "Patient I.D.#";TAB(65);PI$
1340  GOSUB 1345:GOTO 1350
1345  FOR I=1 TO 71:LPRINT "-";:NEXT I:LPRINT:RETURN
1350  LPRINT "Monitor Serial #";TAB(65);SN$
1360  LPRINT "Loaded   on: ";DA$;" @ ";TM$
1370  LPRINT "Unloaded on: ";DATE$;" @ ";TIME$
1380  GOSUB 1345
1390  LPRINT "Dosage Schedule:";
1400  FOR I=1 TO SN:LPRINT "  ";SC$(I-1);:NEXT I
1410  LPRINT:LPRINT "First Dosage:     ";D1$
1415  LPRINT "Start Day Offset:  ";SD
1417  LPRINT "Doses Loaded:      ";DT
1420  LPRINT "Unlock Period:     ";UP$
1430  LPRINT "Alarm Period:      ";AP$
1440  GOSUB 1345
1500  LPRINT:LPRINT "Compliance Profile:"
1510  LPRINT TAB(12);:FOR I=1 TO 59:LPRINT "-";:NEXT I:LPRINT
1520  LPRINT TAB(12);CHR$(124);">2Hr Early
         <2Hr Early   +-1 Hour   <2Hr Late
         >2Hr Late";CHR$(124)
1530  GOSUB 1345
1600  J=51:K=D1;TT=((SD+1)*24+SC(D1))*60
1602  FOR I=1 TO CT
1604  GOSUB 1720
1606  IF TB<>6 THEN 1610
1608  GOSUB 1630:GOSUB 1800:K=K+1:GOSUB 1820:TT=T1:
         GOSUB 1745: GOTO 1606
1610  GOSUB 1630:GOSUB 1800:GOTO 1810
1620  REM --------------------TIME LABEL--------------------
1630  TA$=SC$(K)
1635  IF TB=6 THEN TI$="MISSED":TB=3:RETURN
```

```
1640  IF AH<10 THEN H$="0"+RIGHT$(STR$(AH),1):GOTO 1660
1650  H$=RIGHT$(STR$(AH),2)
1660  IF AM<10 THEN M$="0"+RIGHT$(STR$(AM),1):GOTO 1680
1670  M$=RIGHT$(STR$(AM),2)
1680  TI$=H$+M$
1685  DY=AD-INT(TT/1440)
1690  IF DY=0 THEN 1715
1700  IF DY<0 THEN TI$=TI$+" -"+MID$(STR$(ABS(DY)),2):GOTO 1715
1710  TI$=TI$+" +"+MID$(STR$(ABS(DY)),2)
1715  RETURN
1717  REM ------------UNPACK DATA & ERROR CALC---------------
1720  B1=ASC(D$(J)):IF B1=31 THEN B1=26
1721  B2=ASC(D$(J+1)):IF B2=31 THEN B2=26
1722  B3=B1:GOSUB 1726:AH=B3
1724  B3=B2:GOSUB 1726:AM=B3*2:GOTO 1734
1726  IF B3>127 THEN B3=B3-128
1728  IF B3>63 THEN B3=B3-64
1730  IF B3>31 THEN B3=B3-32
1732  RETURN
1734  AD=0:B3=B2
1736  IF B3>127 THEN AD=AD+32:B3=B3-128
1737  IF B3>63 THEN AD=AD+16:B3=B3-64
1738  IF B3>31 THEN AD=AD+8
1739  B3=B1
1740  IF B3>127 THEN AD=AD+4:B3=B3-128
1742  IF B3>63 THEN AD=AD+2:B3=B3-64
1744  IF B3>31 THEN AD=AD+1
1745  T1=TT+IN(K)*60:R2=((AD*24+AH)*60+AM)-T1
1746  IF R2>-61 THEN TB=6:RETURN
1747  ER=((AD*24+AH)*60+AM)-TT
1750  IF ER>120 THEN TB=5:GOTO 1790
1760  IF ER>60  THEN TB=4:GOTO 1790
1770  IF ER>-61 THEN TB=3:GOTO 1790
1780  IF ER>-121 THEN TB=2:GOTO 1790
1785  TB=1
```

```
1790  RETURN
1795  REM ------------------PRINT LOCATION---------------------
1800  LPRINT CHR$(124);RIGHT$(STR$(I),2);CHR$(124);"  ";TA$;"
        ";CHR$(124);TAB(3+TB*12);TI$;TAB(70);CHR$(124)
1805  RETURN
1810  J=J+2:K=K+1:GOSUB 1820:TT=T1:GOTO 1825
1820  IF K=SN THEN K=0:Z1=I:GOSUB 1345:I=Z1
1822  RETURN
1825  NEXT I
1826  REM ----------------------EXIT-----------------------
1830  GOSUB 1345:LPRINT CHR$(12):LPRINT CHR$(12)
1900  CLS:PRINT @165,"Unload Another Unit? (Y or N)";
1910  PRINT @195,"";:A$=INPUT$(1)
1920  IF A$="Y" THEN CLEAR:GOTO 150
1930  IF A$<>"N" THEN 1910
1940  CLEAR:MENU
2000  IF ERR = 54 THEN 2020
2005  IF ERR=5 THEN 1240
2010  PRINT ERR:PRINT ERL:STOP
2020  CLOSE 1: OPEN "COM:28NID" FOR INPUT AS 1
2025  PRINT "EOF"
2030  RESUME NEXT
```

WHAT IS CLAIMED IS:

1. A dispensing device, comprising:

a storage compartment;

a sleeved strip having a plurality of containers mounted thereon for maintaining a predetermined order of said containers, said sleeved strip and containings being stored within said storage compartment;

dispensing means for dispensing, upon each actuation thereof, one container, said dispensing means including an ejector element mounted for rotation about a longitudinal axis thereof and having container conforming depressions around its periphery, said depressions being shaped so as to engage and convey individual containers arranged in said storage compartment in their order along said sleeved strip; said ejector element, when rotated through a predetermined angle, causing one container to be dispensed and the next container in sequence along said sleeve to be moved into a position ready to be dispensed upon the next ejector rotation; and means for actuating said dispensing means.

2. A device according to claim 1 wherein said storage compartment includes a partition defining a passageway in which said sleeve and containers are stored.

3. A device according to claim 2 wherein said passageway has a width that is less than two container diameters.

4. A device according to claim 1 wherein said ejector element has substantially a cross-sectional form of a square with semicircular depressions in each side of the square for engaging cylindrical-shaped containers.

5. A device according to claim 1 wherein said dispensing means further includes means for preventing rotation of the ejector element in a direction opposite to that of rotation to dispense a container.

6. A device according to claim 1 wherein said dispensing means further includes a stop arrangement, operable in set and reset positions, that prevents after each container is dispensed, further dispensing action until the stop mechanism is reset.

7. A device according to claim 6 further including means for resetting said stop mechanism by means of linkages accessible to a user.

8. A device according to claim 6 wherein the stop mechanism includes latching means for preventing movement of the stop mechanism out of its set or reset positions.

9. A device according to claim 1 wherein said sleeved strip is adapted so that after it is loaded with containers, it can be folded into said storage compartment back and forth across a passageway thereof such that containers earlier in said predetermined order are nearer the dispensing means than containers later in the order.

10. A dispensing device, comprising:

a storage compartment for storing a plurality of containers to be dispensed one at a time in predetermined order;

means, upon an actuation thereof, for dispensing a container from said starage compartment;

means for storing a dispensing schedule specifying when a dispensing operation can be carried out by said dispensing means;

means for alerting a user as to scheduled dispensing times;

means for modifying a schedule stored in said storing means in response to dispensing operations of said dispensing means; and

means for inhibiting operation of said dispensing means other that at time specified by said schedule, as modified.

11. A dispensing device according to claim 10 wherein said alerting means comprises an audible alarm.

12. A dispensing device according to claim 10 wherein said alerting means comprises a visual indicator.

13. A dispensing device, comprising:

storage means for storing a plurality of individual containers;

dispensing means for dispensing one container at a time from said storage means, each container being dispensed by executing an individual dispensing operation;

sequencing means for maintaining a predetermined order among the individual containers so that the individual containers are dispensed in said predetermined order by said dispensing means, said sequencing means also including means for providing a predetermined spacing relationship between containers so that they can be engaged by the dispensing means;

electronic memory means for storing data including instructions for operating the device;

electronic time keeping means for providing time information;

electronic logic means for interpreting and executing said instructions;

means for supplying electrical power to the time keeping means, logic means and memory means; and

a housing containing said storage means, dispensing means, sequencing means, memory means, time keeping means, logic means, and power supplying means.

14. A device according to claim 13 further including means for sensing and signalling for said logic means, each completed dispensing operation of said dispensing means.

15. A device according to claim 13 wherein said storage means includes a substantially 'U' shaped partition defining a passageway.

16. A device according to claim 13 wherein said storage means includes a passageway having a width less than two container diameters.

17. A device according to claim 13 wherein said dispensing means comprises: an ejector element mounted for rotation about a longitudinal axis thereof and having container conforming depressions around its periphery, said depressions being shaped so as to engage and convey individual containers arranged in said storage means in said predetermined order; said ejector element, when rotated through a predetermined angle, causing one container to be dispensed and the next container in sequence to be moved into a position ready to be dispensed upon the next ejector rotation.

18. A device according to claim 17 wherein said ejector element has substantially a cross-sectional form of a square with semicircular depressions in each side of the square for engaging cylindrical-shaped containers.

19. A device according to claim 17 wherein said dispensing means further includes reverse rotation preventing means for preventing potentially harmful rotation of the ejector element in the direction opposite that used to dispense a container.

20. A device according to claim 19 wherein operation of said reverse rotation preventing means, through a common mechanism, simultaneously produces a completed dispensing operation signal.

21. A device according to claim 13 wherein said dispensing means includes a stop arrangement, operable in set and reset positions, that prevents, after each container is dispensed, further dispensing action until the stop mechanism is reset.

22. A device according to claim 21 further including means for resetting said stop mechanism by means of linkages accessible to a user.

23. A device according to claim 21 further including a solenoid and linkages for resetting said stop mechanism under control of said electronic logic means in accordance with said stored instructions thereby controlling the operator's ability to dispense containers, according to said instructions.

24. A device according to claim 23 further comprising a power source separate from said power supplying means for powering the solenoid.

25. A device according to claim 21 wherein the stop mechanism includes latching means for preventing movement of the stop mechanism out of its set or reset positions except as provided for by said instructions.

26. A device according to claim 13 further comprising audible indicating means, controlled by said logic means, for alerting a user as to when a container should be dispensed

according to a predetermined schedule defined by said instructions.

27. A device according to claim 26 wherein said audible indicating means comprises a piezoelectric alarm.

28. A device according to claim 13 further comprising visual indicating means, controlled by said logic means, for prompting a user as to when a container should be dispensed according to a predetermined schedule defined by said instructions.

29. A device according to claim 28 wherein said visual indicating means comprises a liquid crystal display.

30. A device according to claim 13 wherein said sequencing means comprises a thin, flexible strip with regularly spaced sleeves for holding individual containers, one in each sleeve, in a predetermined order.

31. A device according to claim 30 wherein said thin, flexible strip is adapted so that after it is loaded with containers, it can be folded into said storage means back and forth across a passageway thereof such that the containers may be dispensed by the dispensing means in said predetermined order.

32. A device according to claim 14 further comprising second memory means for storing

data, including times of actual dispensing of containers.

33. A device according to claim 32 further comprising communication means for transmitting said data from the device.

34. A device according to claim 13 further comprising communicating means for receiving all or part of said instructions and storing them in said memory means.

35. A device according to claim 14 wherein said sensing and signalling means comprises electrical switches activated by actuators following cams of the dispensing means.

36. A device according to claim 13 wherein the means for supplying electrical power comprises a battery.

37. A device according to claim 13 wherein said storage means is in a portion of said housing that is separable from the remainder of the device to facilitate the use of alternative storage means in an interchangeable manner.

38. A device according to claim 13 wherein the means for supplying electrical power comprises a connector for coupling to an external power source.

39. A device according to claim 13 wherein the housing includes a cabinet lock and tamper-resistant fasteners for preventing

unauthorized access to the containers and mechanisms interior of said housing.

40. A device according to claim 13 wherein said dispensing means is driven manually.

41. A device according to claim 13 wherein said dispensing means is driven primarily by means of power not supplied by a user.

42. A dispensing system comprising:

one or more field units, each field unit including

storage means for storing a plurality of individual containers;

dispensing means for dispensing one container at a time from said storage means, each container being dispensed by executing an individual dispensing operation;

sequencing means for maintaining a predetermined order among the individual containers so that the individual containers are dispensed in said predetermined order by said dispensing means, said sequencing means also including means for providing a predetermined spacing relationship between containers so that they can be engaged by the dispensing means;

electronic memory means for storing data, including instructions for operating the device;

electronic time keeping means for providing time information;

electronic logic means for interpreting and executing said instructions;

means for communicating data to/from said field unit;

means for supplying electrical power to the time keeping means, logic means, memory and communicating means; and

a housing containing said storage means, dispensing means, sequencing means, memory means, time keeping means, logic means, communicating means and power supplying means; and

a base unit for transferring said data to/from said field unit and/or preparing a report of said data sent or received.

43. A system according to claim 42 wherein said field unit further includes means for sensing and signalling to said logic means, each completed dispensing operation of said dispensing means.

44. A system according to claim 42 wherein said storage means includes a substantially 'U' shaped partition defining a passageway.

45. A system according to claim 42 wherein said storage means includes a passageway having a width less than two container diameters.

46. A system according to claim 42 wherein said dispensing means comprises: an ejector element mounted for rotation about a longitudinal axis thereof and having container conforming depressions around its periphery, said depressions being shaped so as to engage and convey individual containers arranged in said

storage means in said predetermined order; said ejector element, when rotated through a predetermined angle, causing one container to be dispensed and the next container in sequence to be moved into a position ready to be dispensed upon the next ejector rotation.

47. A system according to claim 46 wherein said ejector element has substantially a cross-sectional form of a square with semicircular depressions in each side of the square for engaging cylindrical-shaped containers.

48. A system according to claim 46 wherein said dispensing means further includes reverse rotation preventing means for preventing potentially harmful rotation of the ejector element in the direction opposite that used to dispense a container.

49. A system according to claim 48 wherein operation of said reverse rotation preventing means, through a common mechanism simultaneously produces a completed dispensing operation signal.

50. A system according to claim 42 wherein said dispensing means includes a stop arrangement, operable in set and reset positions, that prevents, after each container is dispensed, further dispensing action until the stop mechanism is reset.

51. A system according to claim 50 further including means for resetting said stop mechanism by means of linkages accessible to a user.

52. A system according to claim 50 further including a solenoid and linkages for resetting said stop mechanism under control of said electronic logic means in accordance with said stored instructions thereby controlling the operator's ability to dispense containers, according to said instructions.

53. A system according to claim 52 wherein a power source separate from said power supplying means is used for powering the solenoid.

54. A system according to claim 50 wherein the stop mechanism includes latching means for preventing movement of the stop mechanism out of its set or reset positions except as provided by said instructions.

55. A system according to claim 42 further comprising audible indicating means, controlled by said logic means, for alerting a user as to when a container should be dispensed according to a predetermined schedule defined by said instructions.

56. A system according to claim 55 wherein said audible indicating means comprises a piezoelectric alarm.

57. A system according to claim 42 further comprising visual indicating means, controlled by said logic means, for prompting a user as to when a container should be dispensed according to a predetermined schedule defined by said instructions.

58. A system according to claim 57 wherein said visual indicating means comprises a liquid crystal display.

59. A system according to claim 42 wherein said sequencing means comprises a thin, flexible strip with regularly spaced sleeves for holding individual containers, one in each sleeve, in a predetermined order.

60. A system according to claim 59 wherein said thin, flexible strip is adapted so that after it is loaded with containers, it can be folded into said storage means back and forth across a passageway thereof so that the containers may be dispensed by the dispensing means in said predetermined order.

61. A system according to claim 43 further comprising second memory means for storing data including times of actual dispensing of containers.

62. A system according to claim 61 wherein said communicating means tranmits said data from the device to said base unit.

63. A system according to claim 62 wherein said base unit comprises a general purpose computer, specially programmed to carry out its functions of debriefing said field unit of said data including times of actual dispensing and preparing a report of actual dispensing data.

64. A system according to claim 42 wherein said communicating means receives from the base unit all or part of said instructions for storage in said memory means,

65. A system according to claim 64 wherein said base unit comprises a general purpose computer, programmed to carry out its functions of transmitting all or part of said instructions to said field unit before the field unit is used for dispensing.

66. A system according to claim 43 wherein said sensing and signalling means comprises electrical switches activated by actuators following cams of the dispensing means.

67. A system according to claim 42 wherein the means for supplying electrical power comprises a battery.

68. A system according to claim 42 wherein the means for supplying electrical power comprises a connector for coupling to an external power source.

69. A system according to claim 42 wherein said housing includes a cabinet lock and tamper-resistant fasteners for preventing unauthorized access to said containers and mechanisms interior of said housing.

70. A device according to claim 42 wherein said dispensing means is driven manually.

71. A device according to claim 42 wherein said dispensing means is driven primarily by power not supplied by a user.

72. A system according to claim 42 wherein the storage means is in a portion of the housing that is separable from the remainder of the device, such that alternative storage means, each holding containers of different capacity, may be used interchangeably.

73. A medication dispensing device, comprising:

medication storage means for storing a plurality of individual medication containers arranged in a predetermined sequence;

means for storing a drug therapy schedule defining predetermined times and conditions under which medication containers should be dispensed from said medication storage means;

dispensing means for dispensing from said medication storage means, in response to a patient manipulation thereof at one of said predetermined times of said drug therapy schedule, a medication container;

means for storing information as to the times of actual dispensing of containers for reporting patient compliance with the drug therapy schedule.

74. A device according to claim 73 further including indicator means for indicating to a patient when he should dispense a medication container and administer to himself a medication contained therein.

75. A device according to claim 73 wherein said dispensing means further includes means for preventing the dispensing of a container at times other than said predetermined times of said drug therapy schedule.

76. A device according to claim 74 wherein said indicating means comprises audible alarm means for alerting the patient when one of said predetermined times is near or has passed without a dispensing of a medication container.

77. A device according to claim 76 wherein said audible alarm means comprises a piezoelectric alarm.

78. A device according to claim 73 wherein said therapy schedule further includes instructions for changing the drug therapy schedule in response to a failure of the patient to dispense a medication container at one or more of said predetermined times.

79. A device according to claim 73 further comprising means for transmitting information stored in said storing means.

80. A device according to claim 73 further comprising means for communicating the drug therapy schedule to said drug schedule storage means.

81. A device according to claim 73 wherein said medication containers are vials attached to a belt.

82. A device according to claim 74 wherein said indicator means comprises a digital display for indicating when a next dosage is due to be dispensed according to said schedule.

83. A device according to claim 75 wherein said dispensing means comprises a locking arrangement for blocking free access to said containers; a solenoid for unlocking said locking arrangement so that the dispensing means can be manually manipulated at said predetermined times; and microprocessor means for controlling said solenoid according to said schedule.

84. A device according to claim 73 wherein said dispensing means comprises a sprocket mounted for rotation about a longitudinal axis thereof and having grooves therein for accommodating and conveying said containers.

85. A device according to claim 84 further comprising electrical switches coupled so

as to be actuated by rotation of said sprocket, said switches providing said information as to the times of actual dispensing of containers.

86. A medication dispensing system, comprising:

a base unit for defining a drug dispensing schedule according to which a field unit is to dispense drugs, debriefing the field unit after it has dispensed drugs, and providing a report on the information debriefed; and

a field unit including means for receiving drugs to be dispensed, means for receiving and storing the dispensing schedule from said base unit, means for permitting drugs to be dispensed according to said schedule, means for recording actual times of drug dispensing, and means for transmitting the recorded information to said base unit.

87. A system according to claim 86 further comprising additional field units, each of which can be operated with said base unit.

88. A system according to claim 86 wherein said base unit comprises a computer programmed to carry out its defining, debriefing and reporting functions.

89. A system according to claim 88 wherein said field unit comprises:

medication storage means for storing a plurality of individual medication containers arranged in a predetermined sequence;

means for storing said dispensing schedule;

indicator means for indicating to a user when he should dispense a medication container and administer to himself a medication contained therein; and

dispensing means for dispensing from said medication storage means, in response to a patient manipulation thereof at one of said predetermined times of said schedule, a medication container.

90. A system according to claim 89 wherein said dispensing means further comprises means for preventing the dispensing of a container at times other than said predetermined times of said schedule.

91. A system according to claim 89 wherein said field unit further comprises means for storing information as to the times of actual dispensing of containers for reporting compliance with said schedule.

92. A system according to claim 89 wherein said indicator means includes audible alarm means for alerting the user when a dispensing time is near or has passed without a dispensing of a medication container.

93. A system according to claim 92 wherein said alarm means comprises a piezoelectric alarm.

94. A system according to claim 89 wherein said field unit further includes means for

changing the dispensing schedule in response to a failure of the patient to dispense a medication container at a dispensing time.

95. A system according to claim 89 wherein said medication containers are vials attached to a belt.

96. A system according to claim 89 wherein said indicator means comprises a digital display for indicating when a next dosage is due to be dispensed according to said schedule.

97. A system according to claim 90 wherein said dispensing means comprises a locking arrangement for blocking free access to said containers; a solenoid for unlocking said locking arrangement so that the dispensing means can be manually manipulated at said predetermined times; and microprocessor means for controlling said solenoid according to said schedule.

98. A system according to claim 89 wherein said dispensing means comprises a sprocket mounted for rotation about a longitudinal axis thereof and having grooves therein for accommodating and conveying said containers.

99. A system according to claim 98 further comprising electrical switches coupled so as to be actuated by rotation of said sprocket, said switches providing said information as to the times of actual dispensing of containers.

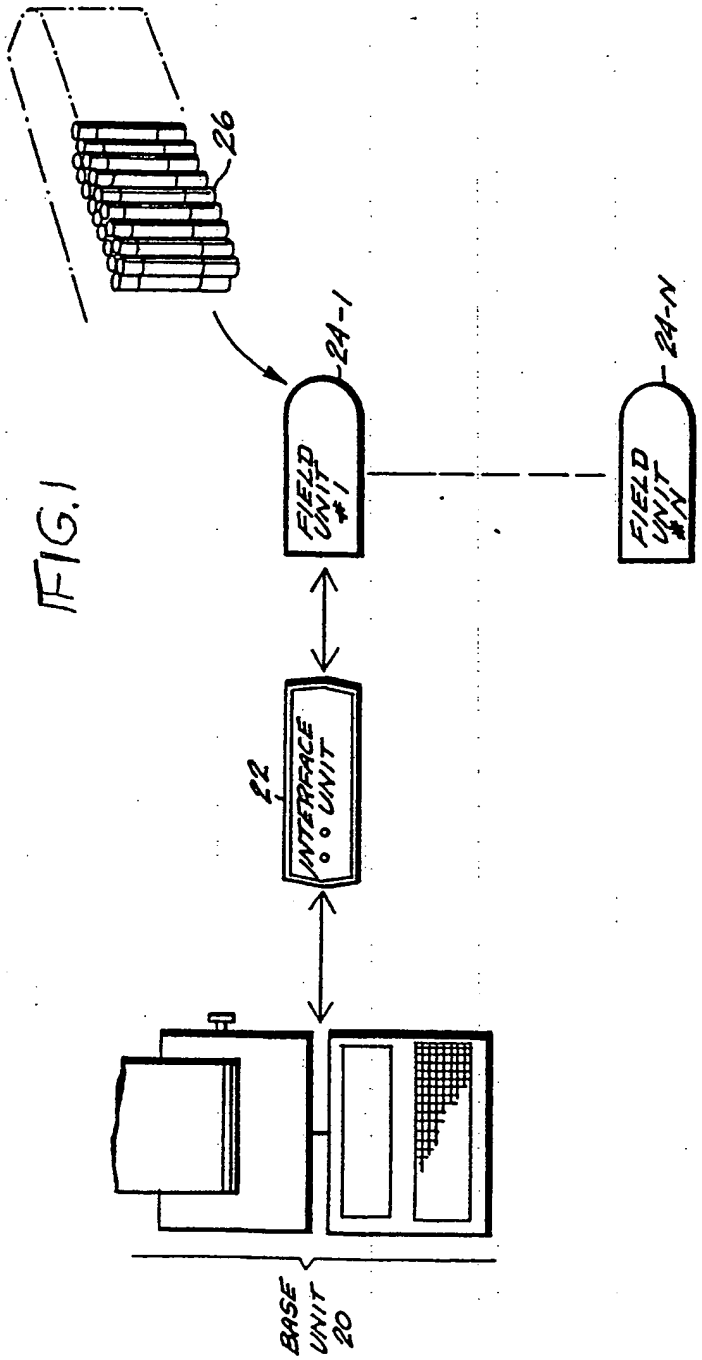

26
24-1
FIELD UNIT #1
24-N
FIELD UNIT #N
22
INTERFACE UNIT
BASE UNIT 20

FIG. 1

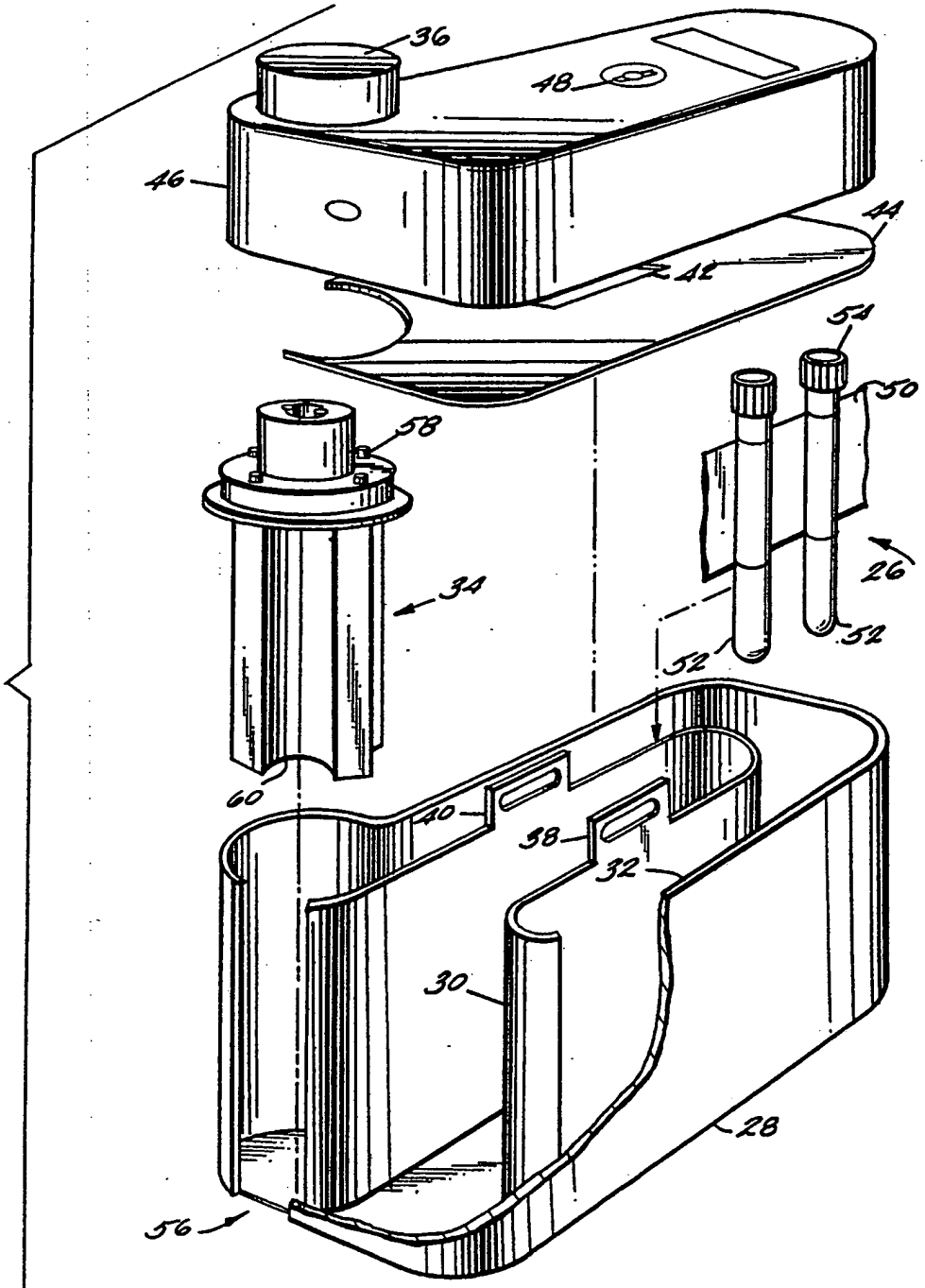


FIG. 2

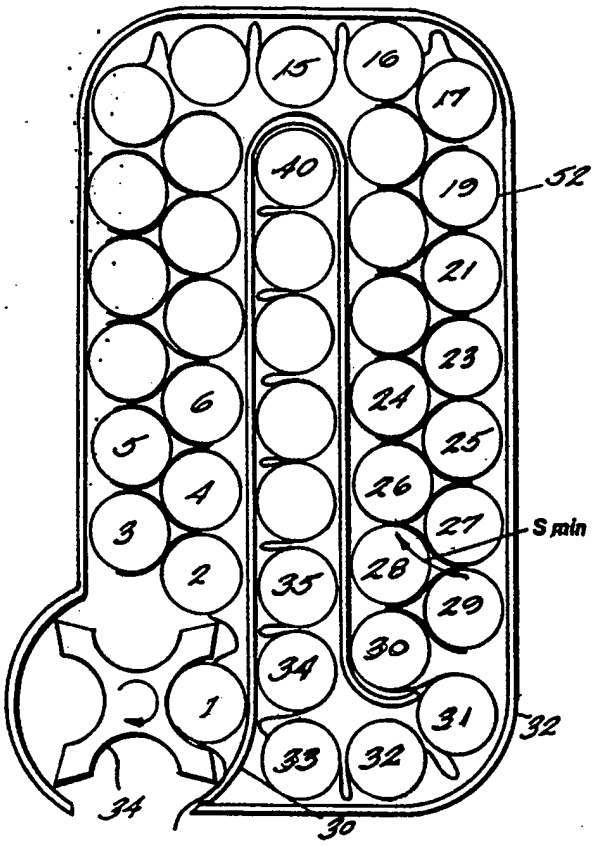


FIG. 4

FIG. 3

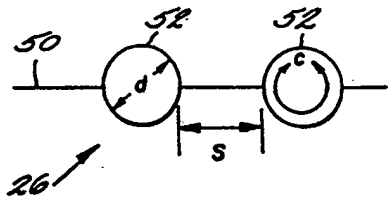


FIG. 5

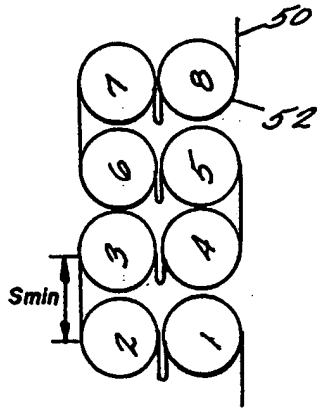


FIG. 7

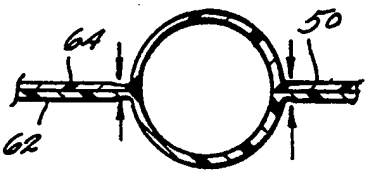
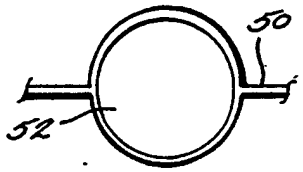


FIG. 6



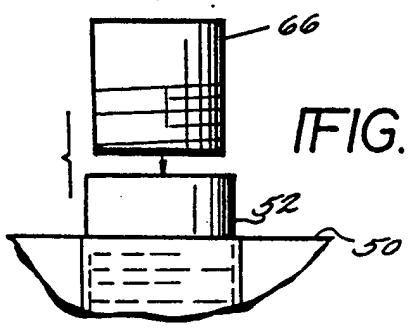


FIG. 9

FIG. 8

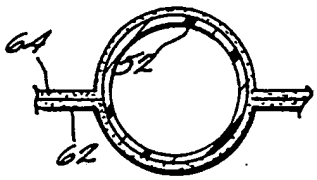


FIG. 10

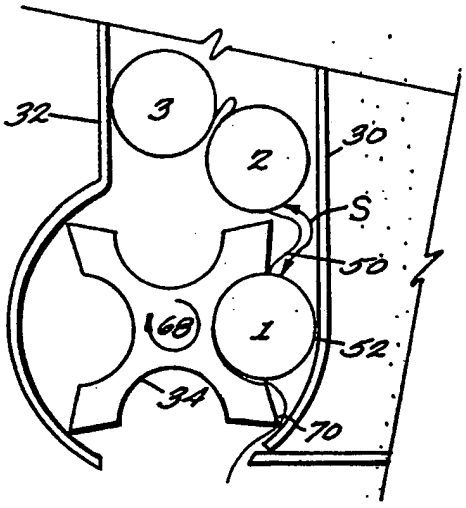


FIG. 11

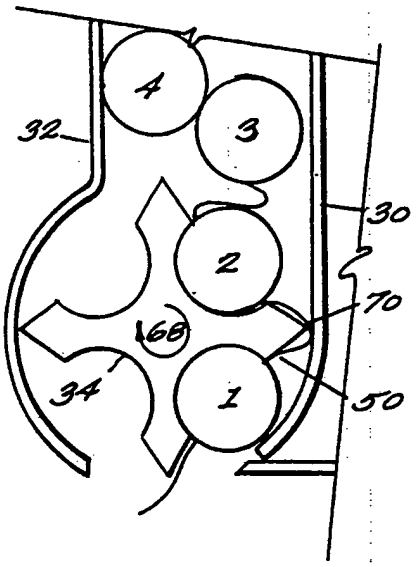
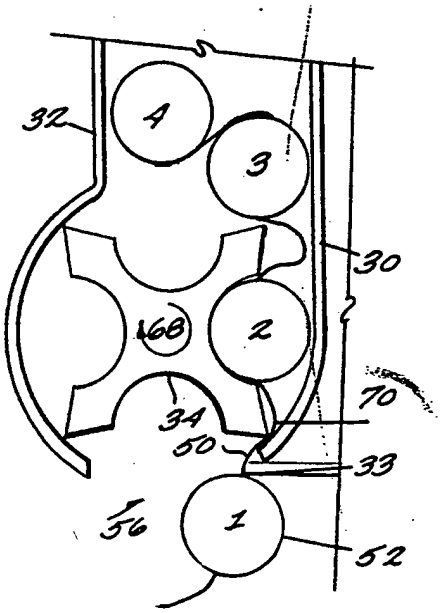


FIG. 12



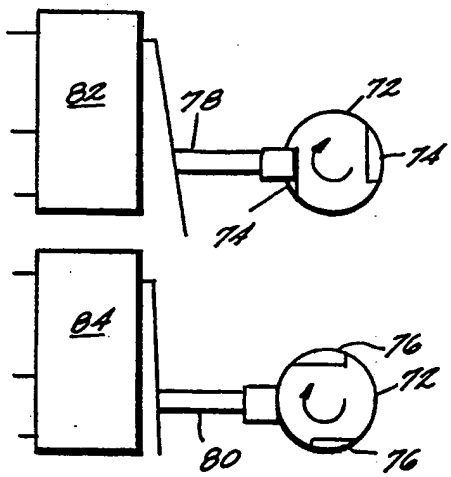


FIG. 15

FIG. 16

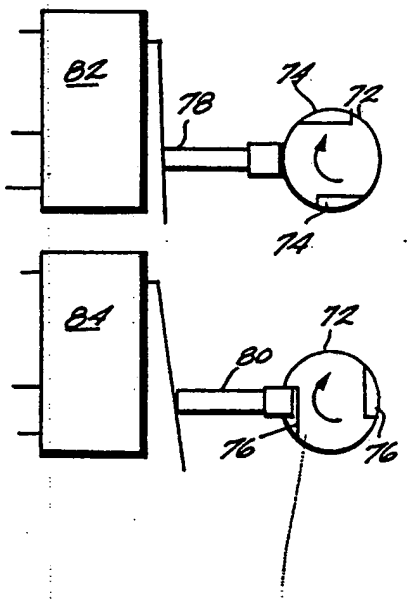


FIG. 13

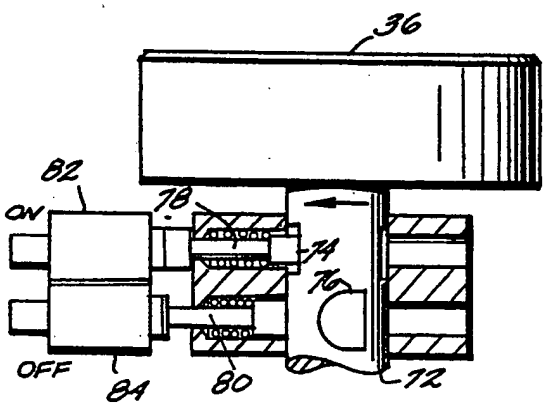


FIG. 14

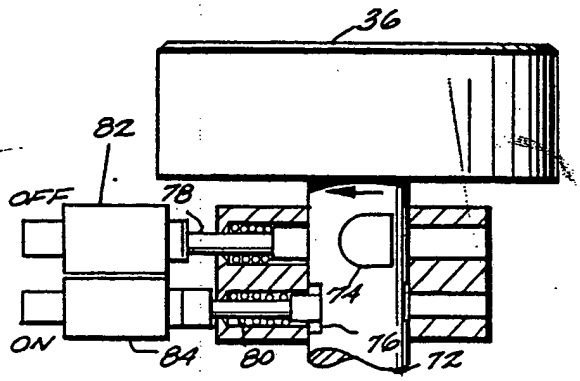


FIG. 17

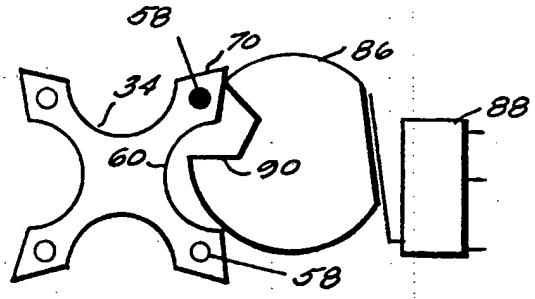


FIG. 18

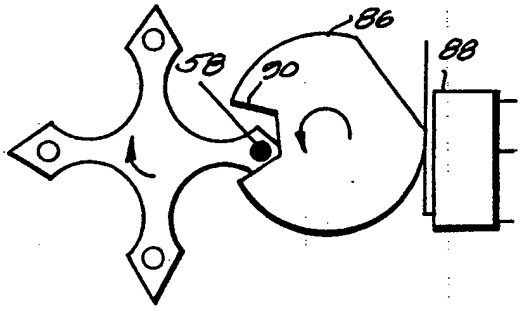


FIG. 19

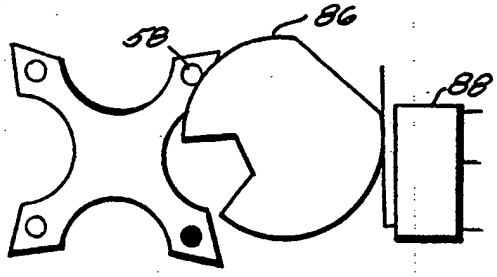


FIG. 20

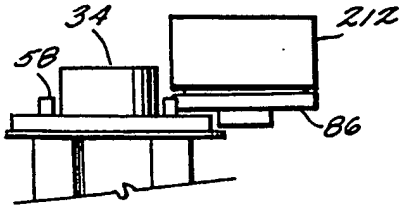


FIG. 21

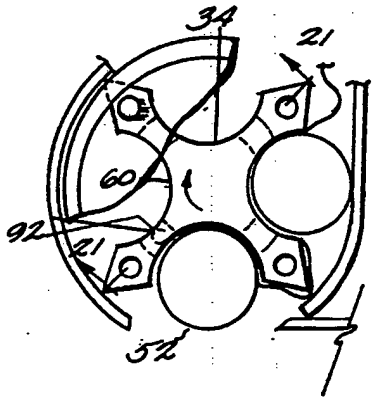


FIG. 22

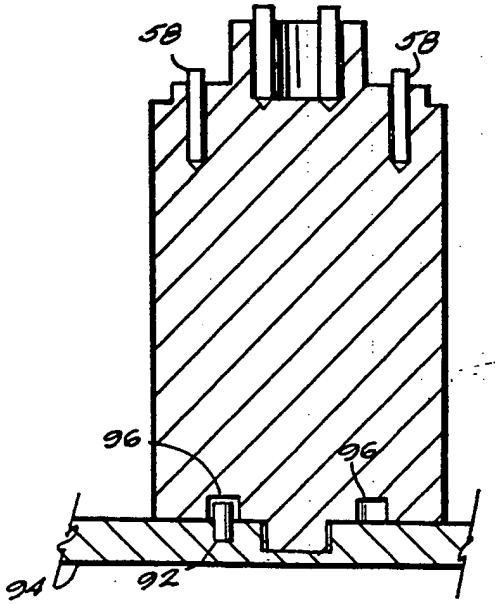


FIG. 24

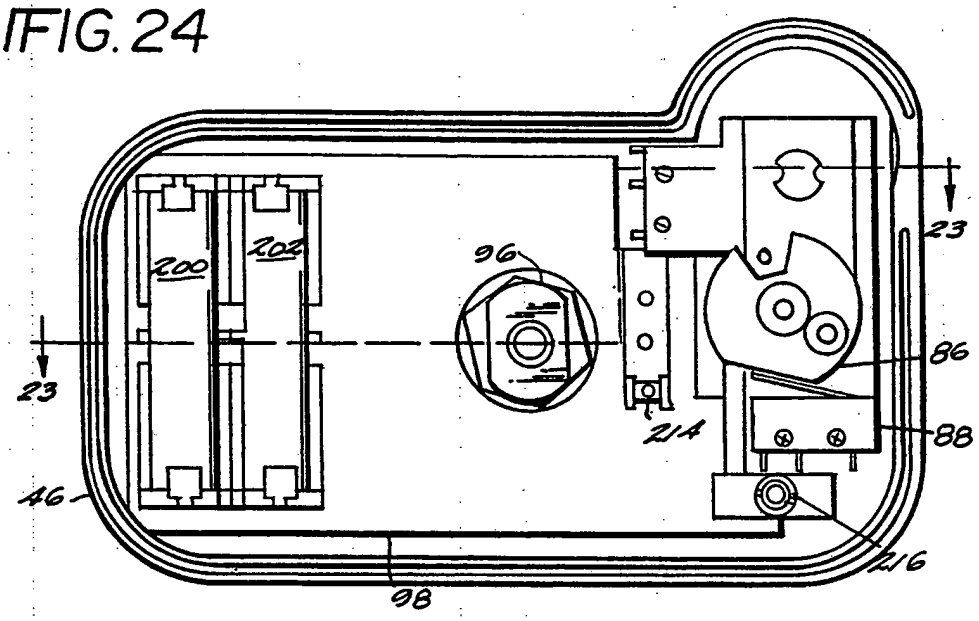

200
202
96
23
23
86
88
214
46
216
98

FIG. 23

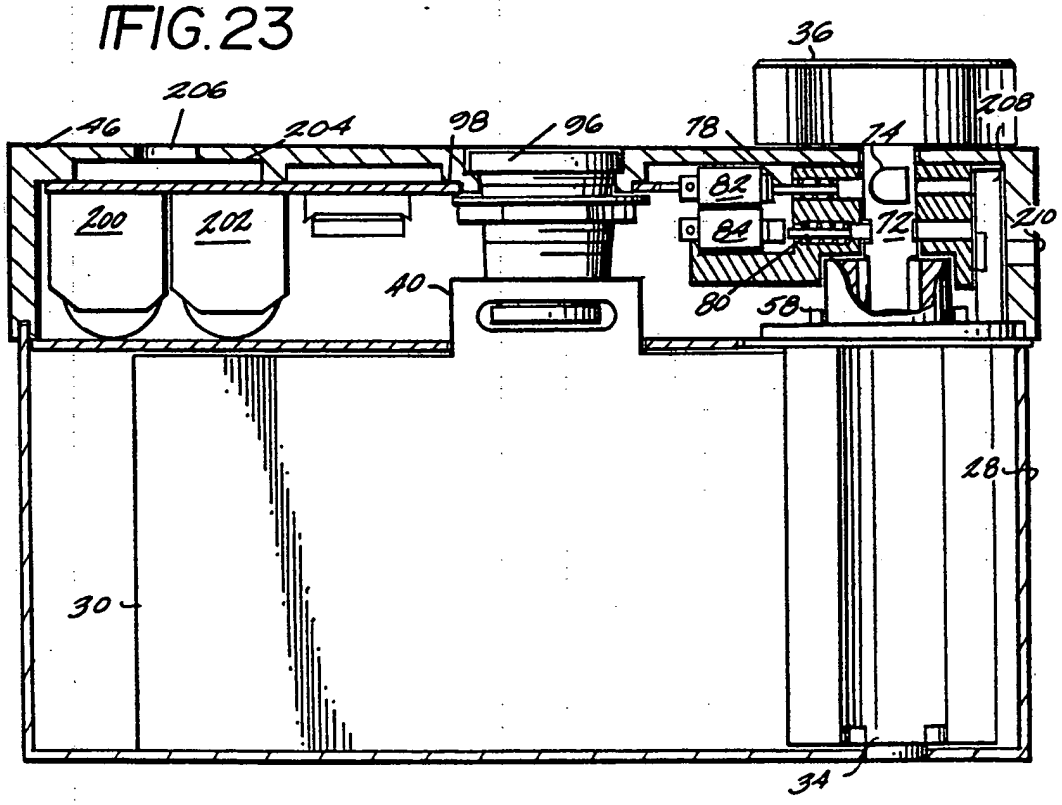
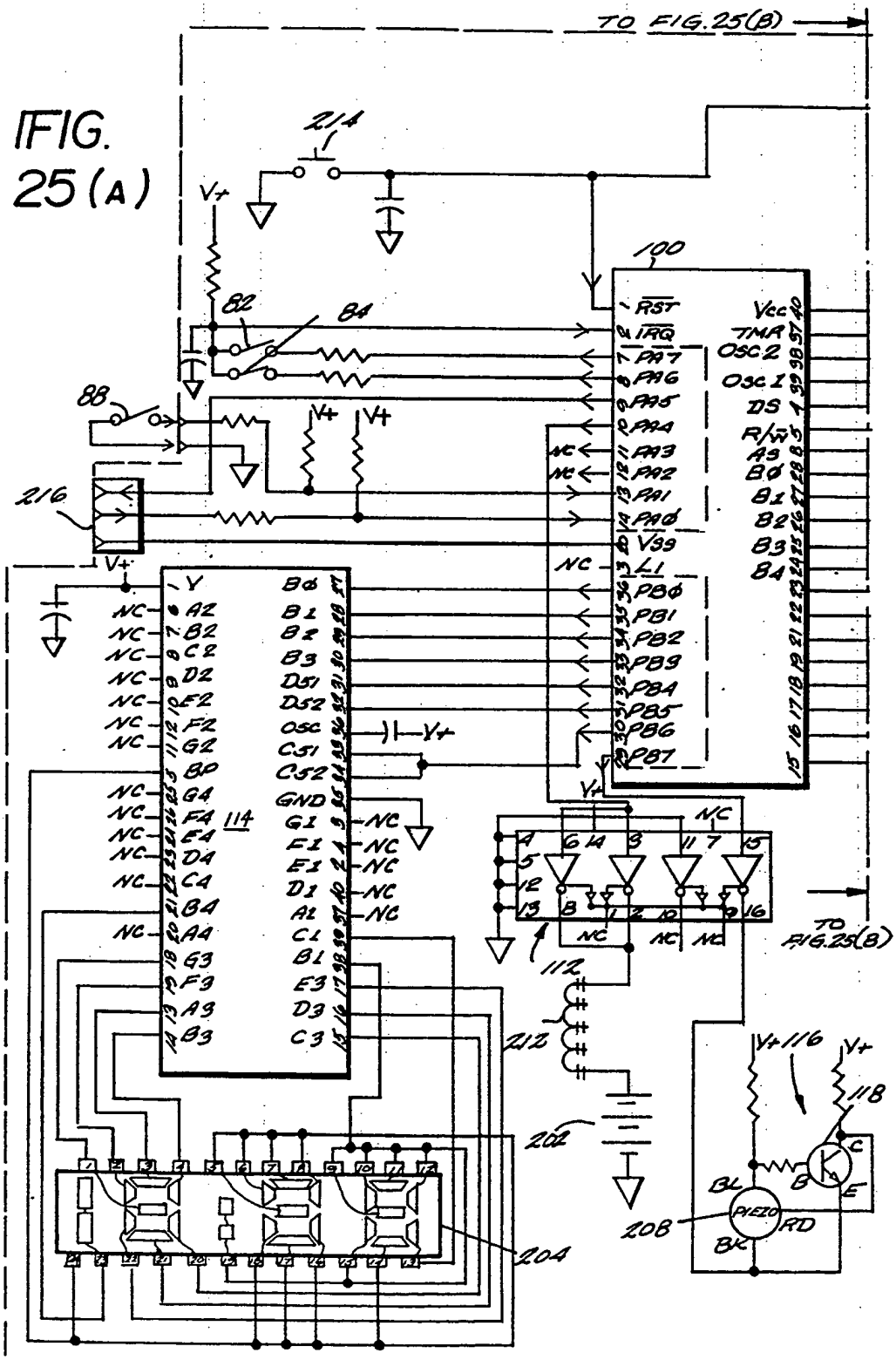

36
206
208
46
204
98
96
78
74
200
202
82
84
72
210
40
80
58
18
30
34

FIG. 25(A)


TO FIG. 25(B)
214
V+
100
82
84
88
216
114
112
202
204
116
118
208
PIEZO
BL
BK
RD
TO FIG. 25(B)

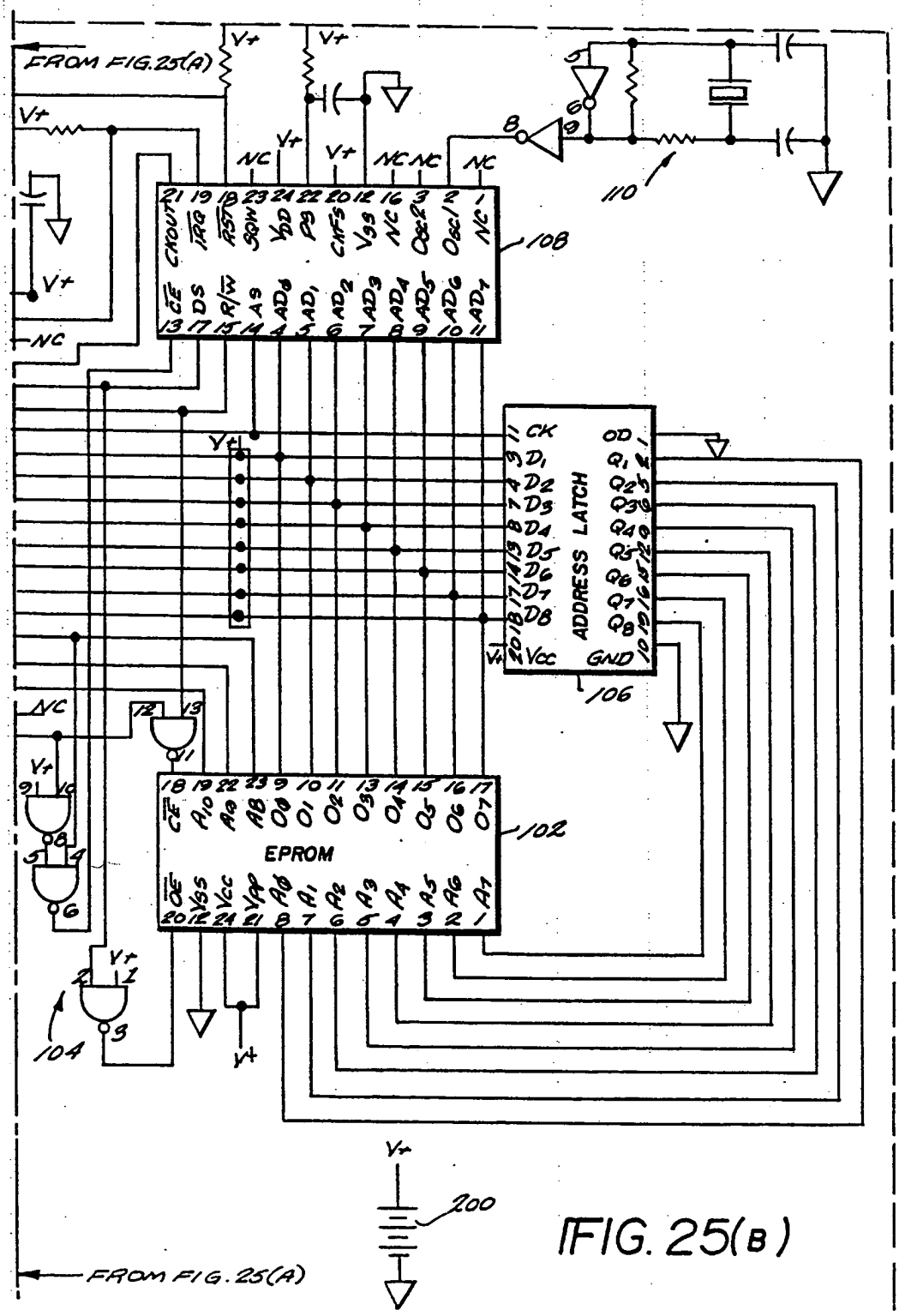

FROM FIG.25(A)
Vt
NC
108
110
ADDRESS LATCH
CK
OD
Vcc
GND
106
EPROM
102
104
200
FROM FIG.25(A)

FIG. 25(B)

FIG.26

(SEE APPENDIX I FOR DETAILED LISTINGS)

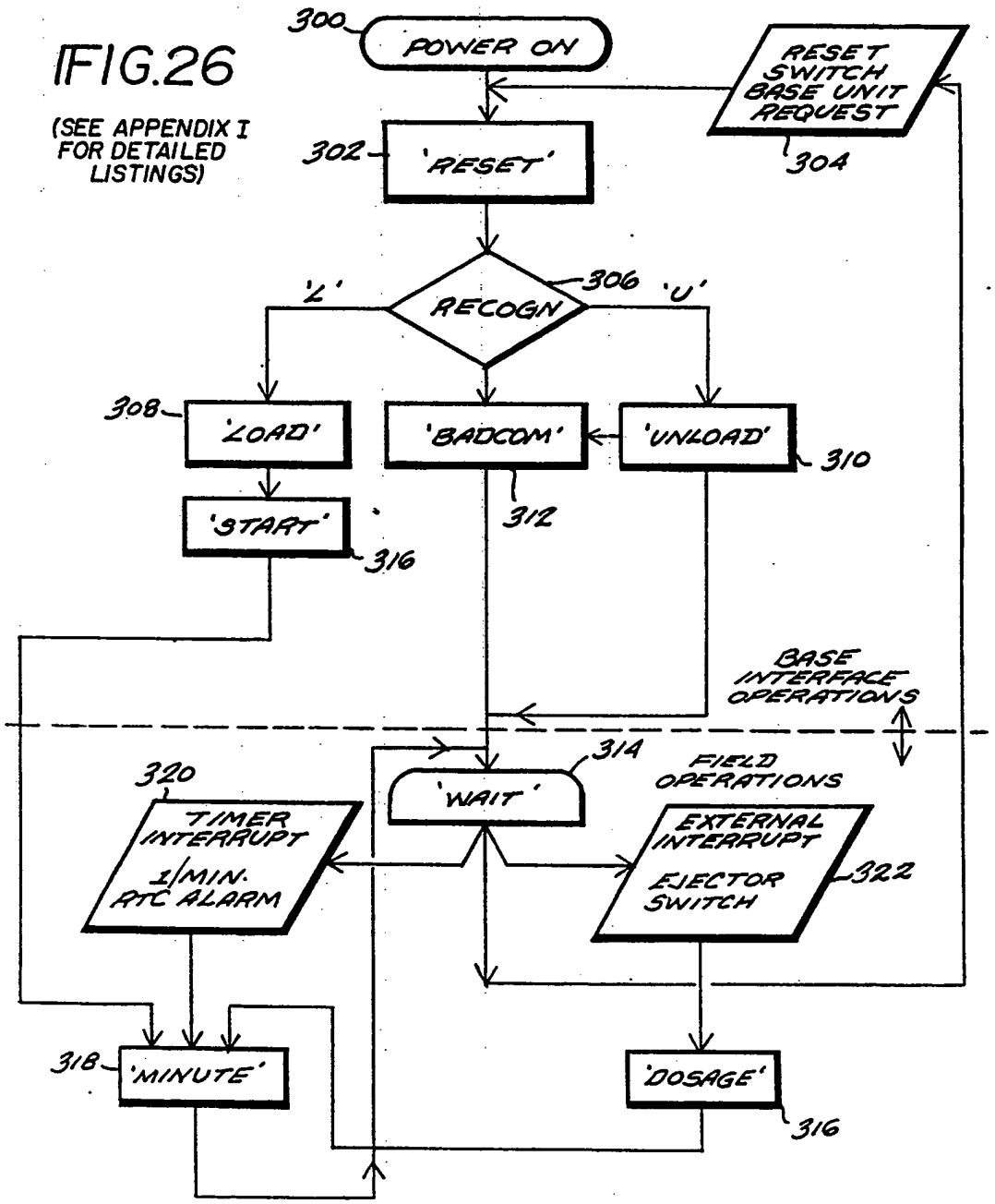
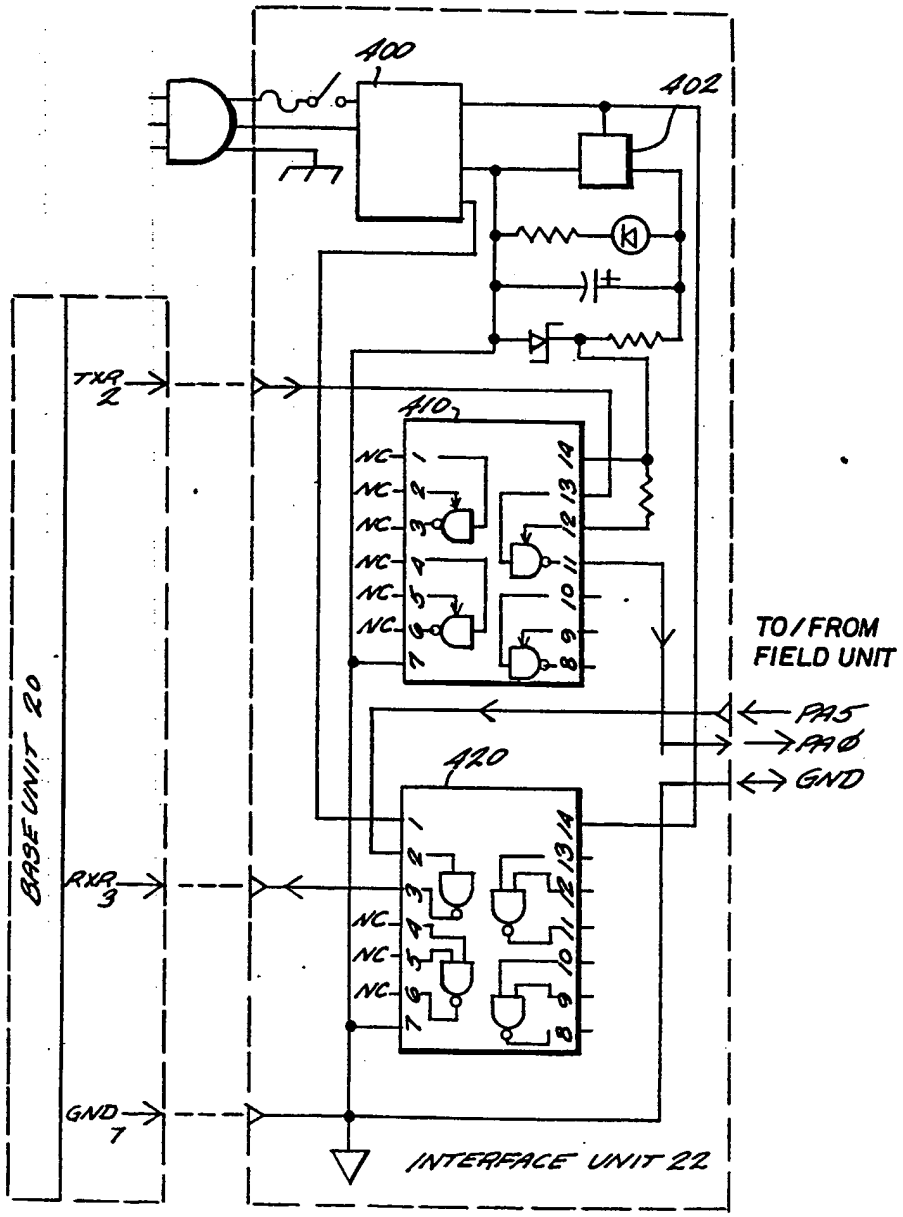


FIG. 27


400
402
410
420
TXR 2
RXR 3
GND 7
BASE UNIT 20
INTERFACE UNIT 22
TO/FROM FIELD UNIT
PA5
PA0
GND
NC

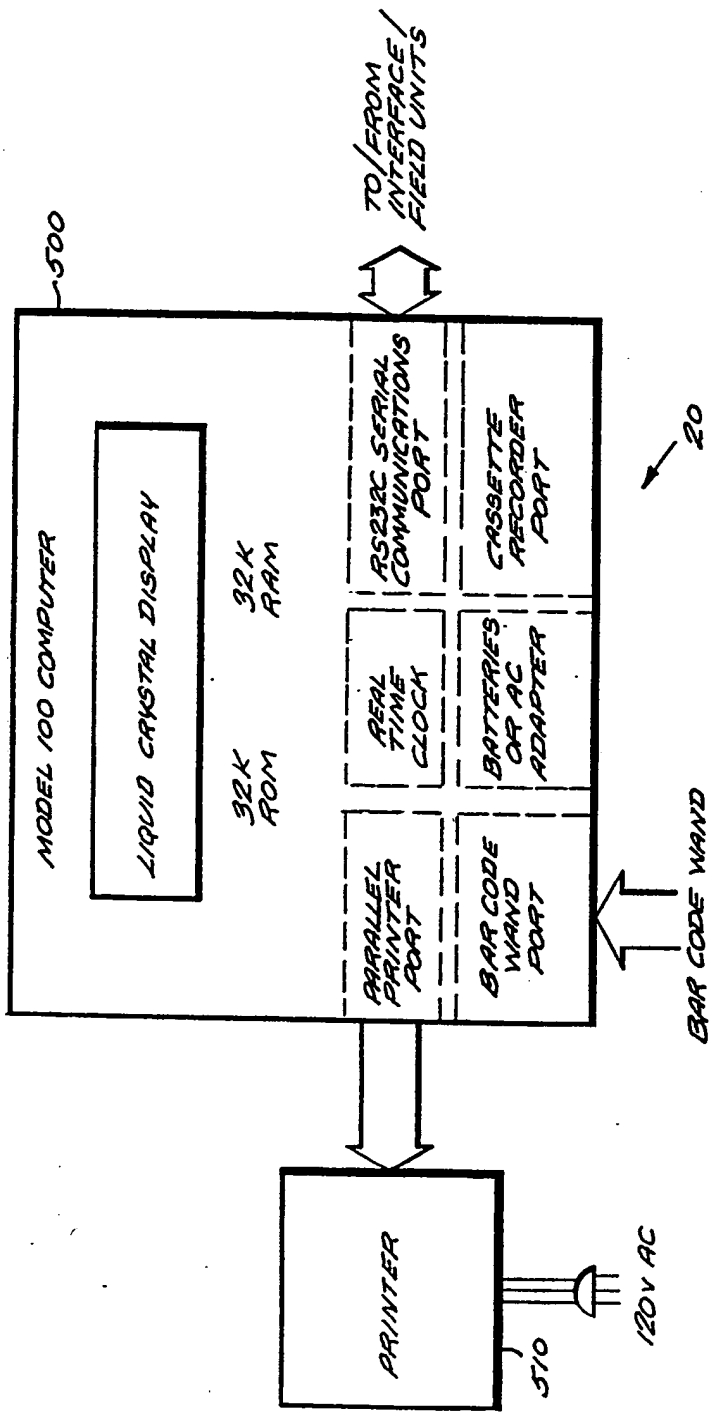

TO/FROM INTERFACE/ FIELD UNITS
500
MODEL 100 COMPUTER
LIQUID CRYSTAL DISPLAY
32K ROM
32K RAM
RS232C SERIAL COMMUNICATIONS PORT
CASSETTE RECORDER PORT
REAL TIME CLOCK
BATTERIES OR AC ADAPTER
PARALLEL PRINTER PORT
BAR CODE WAND PORT
20
BAR CODE WAND
PRINTER
510
120V AC

FIG. 28

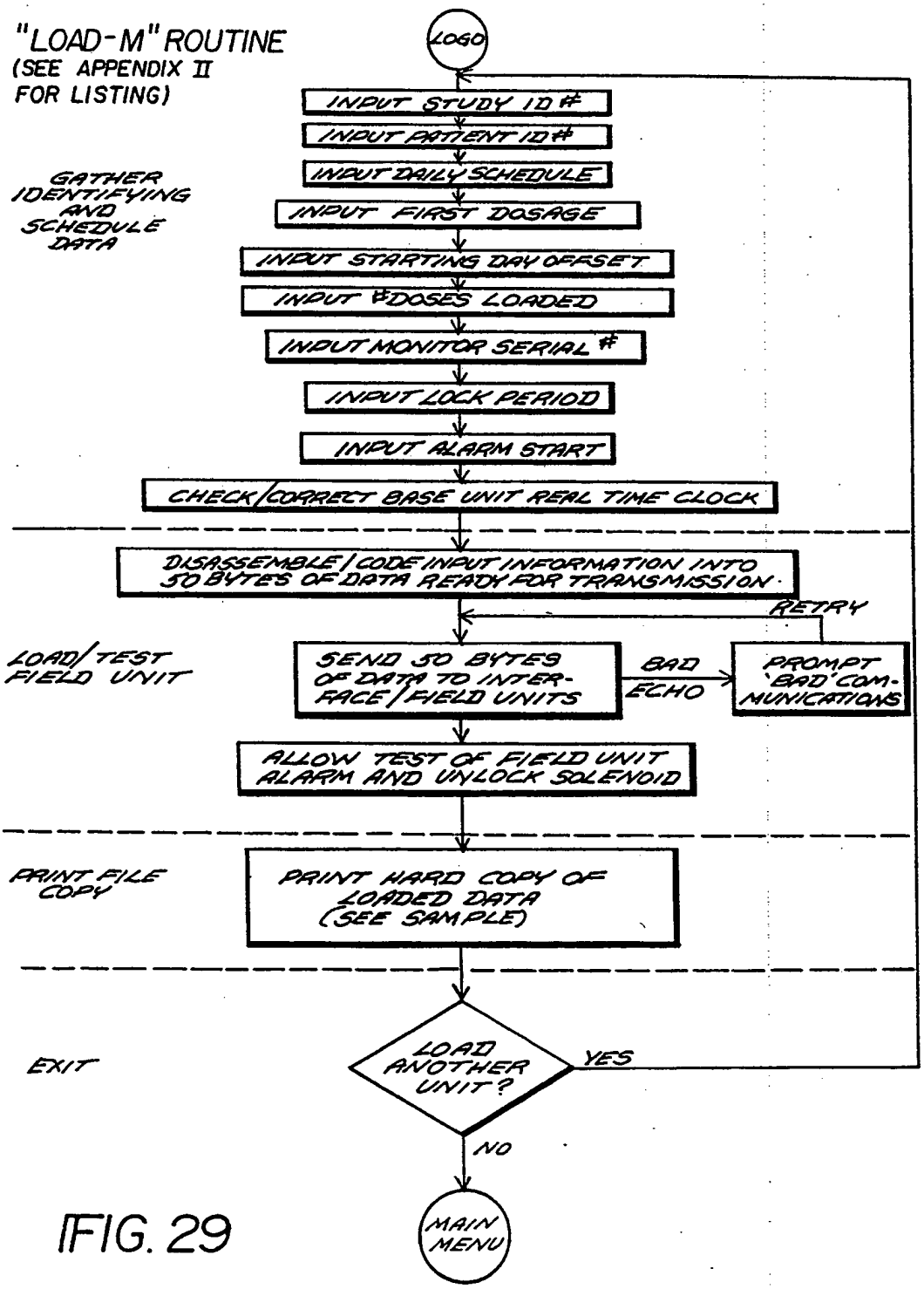

"LOAD-M" ROUTINE
(SEE APPENDIX II FOR LISTING)
LOGO
INPUT STUDY ID #
INPUT PATIENT ID #
INPUT DAILY SCHEDULE
INPUT FIRST DOSAGE
INPUT STARTING DAY OFFSET
INPUT #DOSES LOADED
INPUT MONITOR SERIAL #
INPUT LOCK PERIOD
INPUT ALARM START
CHECK/CORRECT BASE UNIT REAL TIME CLOCK
GATHER IDENTIFYING AND SCHEDULE DATA
DISASSEMBLE/CODE INPUT INFORMATION INTO 50 BYTES OF DATA READY FOR TRANSMISSION
RETRY
LOAD/TEST FIELD UNIT
SEND 50 BYTES OF DATA TO INTERFACE/FIELD UNITS
BAD ECHO
PROMPT 'BAD' COMMUNICATIONS
ALLOW TEST OF FIELD UNIT ALARM AND UNLOCK SOLENOID
PRINT FILE COPY
PRINT HARD COPY OF LOADED DATA (SEE SAMPLE)
EXIT
LOAD ANOTHER UNIT?
YES
NO
MAIN MENU

FIG. 29

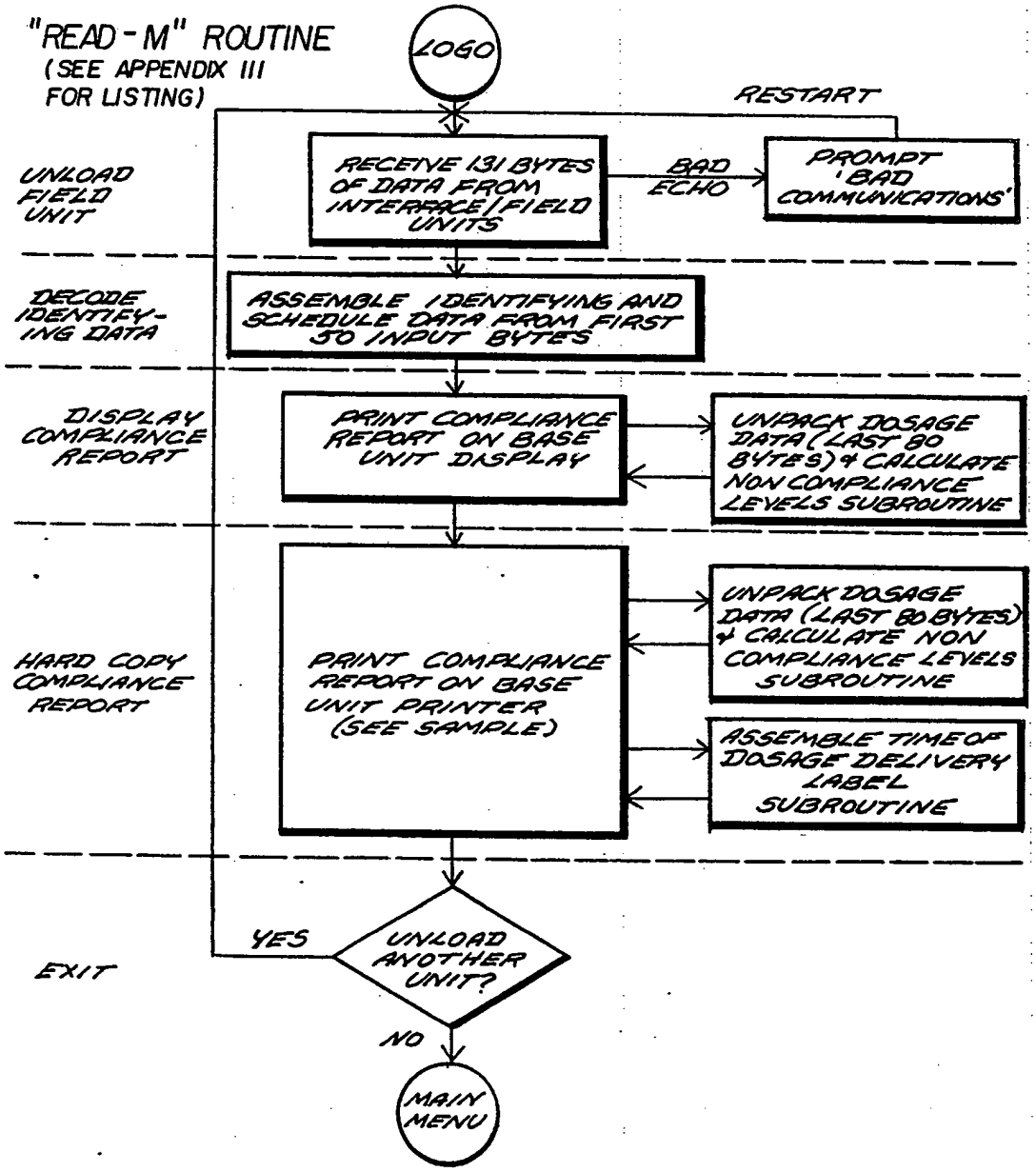

"READ-M" ROUTINE
(SEE APPENDIX III
FOR LISTING)
LOGO
RESTART
UNLOAD FIELD UNIT
RECEIVE 131 BYTES OF DATA FROM INTERFACE/FIELD UNITS
BAD ECHO
PROMPT 'BAD COMMUNICATIONS'
DECODE IDENTIFY-ING DATA
ASSEMBLE IDENTIFYING AND SCHEDULE DATA FROM FIRST 50 INPUT BYTES
DISPLAY COMPLIANCE REPORT
PRINT COMPLIANCE REPORT ON BASE UNIT DISPLAY
UNPACK DOSAGE DATA (LAST 80 BYTES) & CALCULATE NON COMPLIANCE LEVELS SUBROUTINE
HARD COPY COMPLIANCE REPORT
PRINT COMPLIANCE REPORT ON BASE UNIT PRINTER (SEE SAMPLE)
UNPACK DOSAGE DATA (LAST 80 BYTES) & CALCULATE NON COMPLIANCE LEVELS SUBROUTINE
ASSEMBLE TIME OF DOSAGE DELIVERY LABEL SUBROUTINE
YES
UNLOAD ANOTHER UNIT?
EXIT
NO
MAIN MENU

FIG. 30

INTERNATIONAL SEARCH REPORT

International Application No PCT/US86/00711

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.4 B65D 83/04
U.S. Cl. 221/3

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	186/55 206/531, 532, 534 221/3, 5, 9, 13, 15, 25, 30-31, 71-74, 265-266 340/309.3, 309.4, 309.15 364/479

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
Y	US, A, 3,917,045, (Williams), 04 November 1975.	1-5, 9-20, 26-49, 84-89, 92-96, 98.
Y,P	US, A, 4,572,403, (Benaroya), 25 February 1986.	10-20, 26-49, 55-82, 84-89, 92-96, 98
Y	US, A, 2,941,643, (Donnelly), 21 June 1960.	1-5, 9, 17-20, 35, 46-49, 66, 73, 98
Y	US, A, 3,984,030, (Morini), 05 October 1976.	31, 60
Y	US, A, 3,985,264, (Shaw), 12 October 1976.	32-33, 61-63, 73-82, 86-89, 92-93, 95-96

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
26 June 1986	02 JUL 1986
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	Michael S. Huppert 6-30-86 Michael S. Huppert

Form PCT/ISA/210 (second sheet) (October 1981)

International Application No.

PCT/US/86/00711

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category*	Citation of Document, 16 with indication, where appropriate, of the relevant passages 17	Relevant to Claim No 18
Y	US, A, 1,845,879, (Knee), 16, February 1932	40, 70
Y	US, A, 3,815,780, (Bauer), 11 June 1974	94
A,	US, A, 772,503, (Dodson), 18 October 1904	
A	US, A, 3,369,697, (Glucksman) 20, February 1968	
A	US, A, 3,968,900, (Stambuk), 13 July 1976	

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers ....., because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers ....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

The lack of unity of invention holding, set forth on PCT/ISA/206 is hereby withdrawn.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.